IMPLEMENTATION OF THE FOOD SECURITY PROVISIONS OF THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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CONTENTS

IMPLEMENTATION OF THE FOOD SECURITY PROVISIONS OF THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT

FRIDAY, JUNE 25, 2004

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:34 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Shimkus, Brown, Stupak, Green, and Capps.

Staff present: Nandan Kenkeremath, majority counsel; Jeremy Allen, policy coordinator; Ryan Long, majority professional staff; Michael Abraham, legislative clerk; Edith Holleman, minority counsel; and Voncille Hines, minority professional staff.

Mr. BILIRAKIS. I am going to call this hearing to order. Mr. Brown, as I understand it, is on his way. So he will probably be here before I finish up.

This morning we will hold our second hearing this year on Homeland Security programs within this committee's jurisdiction. In May, we held a legislative hearing focused on ways to improve H.R. 3266, the Faster and Smarter Funding for First Responders Act, a bill originally drafted by the Select Committee on Homeland Security. Subsequent to our hearing, changes were made to that legislation to address the concerns this committee had with the legislation, which we supported.

Today, however, we will be focusing on the implementation of one of the most important pieces of legislation this committee has produced over the past several years. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 represents Congress' bipartisan response to the dire threat caused by biological, chemical, and radiological weapons. This law has gone a long way toward improving our ability to prevent an attack of this nature. This hearing will focus on the food safety provisions contained in the act.

Congress provided the Food and Drug Administration with new authority to ensure the safety of our food supply. Specifically, the new law requires the registration of food processors, the prior notification of proposed food imports, the establishment and maintenance of records, and new administrative food detention authority.

The FDA published two interim final rules on October 10 of last year to implement these provisions.

I am pleased that Dr. Lester Crawford, the Acting Commissioner of the FDA, is here to discuss these regulations with us this morning. It is always a pleasure to welcome you to our subcommittee, sir.

These rules are designed to help domestic and foreign food establishments minimize the risk that food under their control could be subject to intentional contamination.

The rules were implemented on December 12, 2003, but, as I am sure Dr. Crawford will point out, FDA has asked its inspectors to flexibly enforce while affected establishments and traders become accustomed to the new system. I am also interested in learning more about the extended education program here and abroad to inform participants along the farm to table continuum about the new requirements.

I am also glad that Ms. Cathy Sauceda, the Director of the Special Enforcement Division of the U.S. Bureau of Customs and Border Protection, is here. Your insight of course into the collaboration between FDA and Customs should prove valuable, and we certainly welcome you here this morning.

As we work to fine-tune our Nation's ability to respond to attacks on our homeland, I am very interested in how different agencies interact. While we can do great things when agencies with differing expertise work together, I want us all to remain vigilant in ensuring that duplication of efforts doesn't result in wasted resources.

Finally, I am pleased that our second panel contains a number of affected stakeholders. I know that the food processing and distribution industry have worked closely with Congress and with the FDA to ensure that the 2002 Bioterrorism Prevention Act is properly implemented. I am aware of your testimony that some of you do have concerns, and I am interested in hearing them. And I would hope, by the way, Dr. Crawford, at this point I realize—I know that you have to leave, and we will let you go just as soon as you have to leave, about 10:30. But if you could have someone from your office stay in the audience so they might take notes as we listen to these affected stakeholders, it could really be helpful. Thank you.

Open dialog between all interested parties is critical to the success of the law. This is an important hearing, and I want to once again—we worked late last night, to well after midnight, and so I think people will be streaming in little by little. But in any case, that is the reason we have hardly anyone else here. But I do want to thank you again for joining us this morning. And, with that, I am very happy to yield to the ranking member for an opening statement. He looks pretty good for having been up that late.

Mr. BROWN. Thanks, Mr. Chairman.

Food security provisions of the 2002 bioterrorism law recognize the very real challenge of food import security, and they give the FDA the tools to meet that challenge. The task before you and for us is a challenging one, to be sure. Protecting the food supply of a country as big and open as the United States from the threat of bioterrorism is a difficult proposition. Fifteen percent of vegetables consumed in the U.S. are imported, 40 percent of the food we eat,

55 percent of the seafood that we consume. In all, we import 5 million shipments of food every year under FDA's jurisdiction. The challenge we face is a serious one but not insurmountable.

The 2002 law gives FDA powerful new legal tools. It requires foreign facilities that are in America's food chain to register with the FDA, requires importers to give FDA prior notice before shipment arrives, requires that businesses in our food chain maintain records necessary to permit effective trace-backs in an emergency, allows detention of a shipment if FDA believes it may pose a threat, and allows FDA to disbar companies with a track record of noncompliance.

FDA has received hundreds of millions of dollars in additional appropriations to implement the new law, and FDA has used these resources to both beef up technology, improve systems, and hire hundreds of new field agents, lab analysts, criminal investigators, and other professionals who can put these new security protections into effect. So I say one of the strengths of the 2002 act is its flexibility. The law gives FDA significant discretion in key areas to ensure that requirements like facility registration and prior notice are tailored to provide maximum protection for the public and minimum compliance burden for industry.

Industry has raised some concerns about the actual implementation. These are serious considerations, and as this hearing demonstrates, Congress is serious about getting the implementation with you right.

But let me be clear. The 2002 act gives FDA ample flexibility to address legitimate concerns. I stand ready to work with industry to improve the system within the framework of current law, And I look forward to the testimonies of our witnesses.

Mr. BILIRAKIS. I thank the gentleman, and I would now yield to the gentleman from Illinois, Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman.

And I guess one of the few conferences that I was ever to be able to be a part of was this one, and so I am here with great interest to hear how the legislation and actually the implementation is moving forward.

We have a great food safety program here in this country. The concerns of the world are still prevalent and very evident. I, like many, will want to ensure that, as best as possible, that we are maintaining that food safety supply without that now that very dangerous opportunity of destroying the small businesses that will become overwhelmed by the bureaucratic efforts to maintain them in this new environment. I think there is great concern. The more government we have to have to intervene to protect, really, the bigger the organizations have to be and the larger staffs and the more legal advice and the more clerks to comply. And that is good in major corporations of large sizes, but as we say so much here in Washington, it is the smaller institutions, sole proprietorships, and the partnerships and stuff that people who are trying to administer and make the country grow are also trying to do those other areas. And this area is even more challenging with the safety implications of what we are talking about.

So that is my concern, and I think that will be raised by other members. I look forward to hearing this, and I thank you for your

attendance. And, Mr. Chairman, I yield back the balance of my time.

Mr. BILIRAKIS. I thank the gentleman.

Does Mr. Stupak have an opening statement?

Mr. STUPAK. I will waive, Mr. Chairman.

Mr. BILIRAKIS. Thank you, sir.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you Mr. Chairman for holding this hearing. I would also like to thank our witnesses for agreeing to testify about this important subject.

The terrorist attacks of September 11, 2001, and the subsequent anthrax attack on the Capitol transformed our understanding of the threats facing our nation. We have been forced to assess the risks of unconventional attacks that were previously un-imagined. We have also identified frightening vulnerabilities that could be used to threaten the safety of millions of Americans.

One area of particular concern that was identified after 9-11 was the vulnerability associated with a possible terrorist threat to our food supply. Under the leadership of this Committee, Congress responded to this threat by passing the Public Health Security and Bioterrorism Preparedness and Response Act.

The new law will protect our food supply by broadening the FDA's authority to better track and prevent potential food adulteration and to give the agency more information about the food supply. The new law authorizes FDA to register food processors, require advance notification on imports and impound suspicious shipments.

The new law will require continuing collaboration between industry, the regulating agencies, and Congress in order to allow the successful implementation of the new requirements.

This hearing will provide a forum to discuss implementation of the Act up to this point, and allow for comments on how best to proceed forward. I am pleased to hear that the FDA has been receptive to industry suggestions on how to implement the Bioterrorism Act. I also want to learn the status of current efforts to register food processors in order to ensure a seamless transition to the new regulatory structure that is slated to begin in August.

Congress, the Administration, and industry have an obligation to continue to work together to balance the economic demands for the free flow of commerce while securing our nations food supply. This hearing will provide us with an opportunity to review all of our efforts to date and determine what more needs to be done. Thank you again Mr. Chairman for holding this important hearing and I yield back the balance of my time.

Mr. BILIRAKIS. Let us go right into the panel then.

The first panel consists of, as I have already indicated, Dr. Lester Crawford, as the Acting Commissioner of the FDA, and Ms. Cathy Sauceda, Director of the Special Enforcement Division with U.S. Customs and Border Protection.

I am going to set the clock to 5 minutes, but by all means, if you haven't completed your statement, please continue on. Don't worry about the time.

Dr. Crawford, we will start off with you. Thank you, sir. Your written statements of course are a part of the record, so we would hope you would complement and supplement those. And the written opening statements of all members of the subcommittee, without objection, will be made a part of the record.

Please proceed, sir.

STATEMENTS OF LESTER M. CRAWFORD, ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION; AND CATHY SAUCEDA, DIRECTOR, SPECIAL ENFORCEMENT DIVISION, U.S. CUSTOMS AND BORDER PROTECTION

Mr. CRAWFORD. Thank you very much. It is a pleasure to be here, and I appreciate the invitation, Mr. Chairman, members of the subcommittee. I am also pleased to be here with my colleague Cathy Sauceda from Customs and Border Protection. Thank you very much for all you have done to help us in this effort and to work together.

Thank you for this opportunity to discuss FDA's actions to implement the food safety provisions in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. I wish to thank the members of this subcommittee for your leadership in enacting this landmark legislation. The Bioterrorism Act has provided us with significant new tools to protect the Nation's food supply against the threat of intentional contamination and other food-related emergencies.

FDA regulates 80 percent of the Nation's food supply, everything we eat except for meat, poultry, and certain egg products. FDA's responsibility extends to live food animals and to animal feed.

Since the Bioterrorism Act was signed into law just over 2 years ago, FDA has been working hard to implement this law effectively and efficiently. Section 305 of this act requires registration of foreign and domestic food facilities that manufacture, process, pack, or hold food for consumption by humans or animals in the United States. FDA will have for the first time a roster of foreign and domestic food facilities that provide food for American consumers. In the event of a potential or actual terrorist incident or an outbreak of food-borne illness, the registration information will help FDA to quickly identify, locate, and notify the facilities that may be affected. On October 10, 2003, FDA and CBP jointly published an interim final regulation to implement the registration requirement.

Section 307 of the act requires submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. This advance information enables FDA, working closely with CBP, to more effectively target inspections at the border to ensure the safety of imported foods before they move into the U.S.

On October 10, 2003, FDA and CBP jointly published an interim final regulation to implement this provision. Since this rule became effective on December 12 last, we have processed approximately 4 million prior notice submissions. We recently reopened and extended the public comment period on this rule through July 13, 2004.

Last December, CBP and FDA issued a compliance policy guide that explains our intention to focus initially on educating affected firms and individuals about the new requirement while gradually phasing in enforcement. This phase-in period will end August 12, at which time routine enforcement will begin.

This week, FDA, with CBP concurrence, announced that we would continue our policy of focusing on education for certain non-commercial shipments until the final rule is published. We took this action in response to concerns about different kinds of non-

commercial shipments such as household goods that contain food items and shipments by individuals sent through international mail or express carriers for noncommercial purposes.

Section 306 of the Bioterrorism Act authorizes FDA to have access to certain records when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

On May 9 of last year, FDA published a proposed rule to implement this section. We intend to issue a final rule in the near future. When finalized, the recordkeeping regulations will help FDA track and contain foods that pose a serious threat.

Section 314 of the act authorizes FDA to commission other Federal officers and employees to conduct examinations and investigations. FDA and CBP have signed a memorandum of understanding to commission CBP officers to conduct investigations and examinations on FDA's behalf.

I am pleased to report, Mr. Chairman, that some 8,100 CBP officials have been commissioned and trained in FDA activities. This collaboration significantly strengthens our ability to secure the border while ensuring the movement of legitimate trade.

Section 303 of the Bioterrorism Act gives FDA new authority to administratively detain any article of food for which FDA has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. On June 4 of this year, FDA published a final rule that included expedited procedures for perishable foods as well as procedures describing how FDA will detain an article of food and the process for appealing a detention order.

Thank you very much for having me here. I look forward to comments and questions. Thank you, sir.

[The prepared statement of Lester M. Crawford follows:]

PREPARED STATEMENT OF LESTER M. CRAWFORD, ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION

INTRODUCTION

Good morning, Chairman Bilirakis and Members of the Subcommittee. I am Dr. Lester M. Crawford, Acting Commissioner of the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS or the Department). I am pleased to be here today with my colleague, Ms. Cathy Sauceda from Customs and Border Protection (CBP) in the Department of Homeland Security (DHS). Thank you for this opportunity to discuss FDA's actions to implement the food safety provisions in Title III, Subtitle A—Protection of Food Supply—in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). I wish to thank the Members of this Subcommittee for your leadership in enacting this landmark legislation. This legislation represents the most fundamental enhancement to our food safety authorities in many years. As you know, it provided us with significant new tools to protect the nation's food supply against the threat of intentional contamination and other food-related emergencies. Implementing these new authorities has been a top priority for FDA.

In my testimony today, I will first provide some background on HHS' food safety responsibilities. Then, I will describe the many actions FDA has taken to implement the food safety provisions in the Bioterrorism Act.

HHS' FOOD SAFETY RESPONSIBILITIES

FDA is the Federal agency that regulates 80 percent of the nation's food supply(everything we eat except for meat, poultry, and certain egg products, which are regulated by our partners at the United States Department of Agriculture (USDA).

FDA's responsibility extends to live food animals and animal feed. FDA is also responsible for ensuring that human drugs, human biological products, medical devices, and radiological products as well as veterinary drugs are safe and effective, and that cosmetics are safe. In addition, FDA is responsible for assuring that the health consequences of foods and medicines are accurately and honestly represented to the public, so that they can be used as effectively as possible to protect and improve the public health.

While FDA has the lead responsibility within HHS for ensuring the safety of food products, the Centers for Disease Control and Prevention (CDC) within HHS has an important complementary and non-regulatory public health role. As the lead Federal agency for conducting disease surveillance, CDC monitors the occurrence of illness in the U.S. attributable to the entire food supply. The disease surveillance systems coordinated by CDC, in which FDA participates, provide an essential early-information network to detect dangers in the food supply and to reduce foodborne illness. In addition, these systems can be used to indicate new or changing patterns of foodborne illness. Because CDC detects and investigates outbreaks of foodborne illness through its networks, CDC is able to alert FDA and USDA about implicated food products associated with an outbreak and works closely with the agencies to take protective public health action. In keeping with its agency mission, CDC also identifies, evaluates, and offers expert scientific opinion on the effectiveness of foodborne disease prevention strategies.

FDA contributes to the Foodborne Diseases Active Surveillance Network (FoodNet), the principal foodborne disease component of CDC's Emerging Infections Program (EIP). FoodNet is a collaborative activity of CDC, FDA, the Food Safety and Inspection Service of USDA, and ten EIP sites, (California, Colorado, Connecticut, Georgia, New York, Maryland, Minnesota, Oregon, Tennessee, and New Mexico). Through this active surveillance system, these sites actively seek out information on foodborne illnesses identified by clinical laboratories, collect information from patients about their illnesses, and conduct investigations to determine which foods are linked to specific pathogens. This surveillance system provides important information about changes over time in the burden of foodborne diseases. These data help public health and food safety agencies evaluate the effectiveness of current food safety initiatives and develop future food safety activities. FDA provides both monetary support and technical expertise to the program.

In addition, just as FDA works with Federal, state, and local food safety counterparts, CDC works extensively with Federal, state, and local health departments to build their epidemiology, laboratory, and environmental health expertise in foodborne disease surveillance and outbreak response. All of these collaborations draw on and apply the unique expertise within HHS to address significant and emerging challenges to our food supply.

IMPLEMENTATION OF SUBTITLE A OF TITLE III OF THE BIOTERRORISM ACT

Subtitle A of Title III of the Bioterrorism Act provides the Secretary of Health and Human Services with new authorities to protect the nation's food supply against the threat of intentional contamination and other food-related emergencies. FDA is responsible for implementing these provisions. These new authorities improve our ability to act quickly in responding to a threatened or actual terrorist attack, as well as other food-related emergencies. Since this legislation was signed into law just over two years ago, FDA has been working hard to implement this law effectively and efficiently. Throughout this process, FDA has enjoyed close cooperation from our colleagues at CBP.

Registration of Food Facilities

Section 305 of the Bioterrorism Act requires registration of foreign and domestic food facilities that manufacture, process, pack, or hold food for consumption by humans or animals in the U.S.. Thanks to this provision, FDA will have, for the first time, a roster of foreign and domestic food facilities that provide food for American consumers. In the event of a potential or actual terrorist incident or an outbreak of foodborne illness, the registration information will help FDA to quickly identify, locate, and notify the facilities that may be affected.

On October 10, 2003, FDA and CBP jointly published an interim final regulation to implement the registration requirement. This regulation became effective on December 12, 2003. We have provided two public comment periods that allowed a total of 105 days for interested parties to comment on certain provisions in the interim final rule. We currently intend to publish the final rule in the spring of 2005 after considering all the timely comments we have received.

FDA's electronic registration system became operational on October 16, 2003, which allowed facilities almost two months to register with FDA before the regula-

tion became effective. We worked hard to develop an electronic system that is easy to use. The system is available 24 hours a day, seven days a week, to anyone with access to the Internet. We are also providing technical assistance to persons who need help with the registration process. The electronic system will provide the facility with its registration number nearly instantaneously upon successful completion of the registration process. While facilities are not required to register electronically, FDA strongly encourages facilities to use the electronic system to register. Although it will take longer for facilities that register by mail to receive their registration numbers, registration by paper also is relatively easy to accomplish. As of June 24, 2004, 208,277 facilities have registered. This includes 98,896 domestic and 109,381 foreign facilities.

Our goal has been to phase-in enforcement of the registration rule in a manner that ensures a smooth transition with minimal effect on commerce. Last December, FDA published two Compliance Policy Guides that stated our intention to focus initially on educating industry about how to comply with the new registration requirement. For domestic facilities, FDA expects it typically would discover a registration violation during a routine inspection and would enforce the registration provision as appropriate in each situation. Circumstances that could merit regulatory action include a continuing failure to register or a threat to the food supply associated with food from an unregistered facility. In addition, FDA may consider the failure to register as an additional charge in an enforcement action that is based on other statutory violations. Regarding foreign facilities, Section 305 states that food from a foreign facility that is required to register, but has not done so, must be held at the port of entry until the facility is registered. Accordingly, FDA is enforcing the registration requirement for manufacturers and shippers through the prior notice interim final rule, which I will discuss in a moment. In most cases, the failure of a facility, domestic or foreign, to be registered is a violation that can be readily corrected. As mentioned above, electronic registration may be accomplished with minimal effort. Thus, the ability to remedy a failure to register is relatively straightforward for both domestic and foreign facilities.

Prior Notice of Imported Food Shipments

Section 307 of the Bioterrorism Act requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the U.S. This advance information enables FDA, working closely with CBP, to more effectively target inspections at the border to ensure the safety of imported foods before they move into the U.S. On October 10, 2003, FDA and CBP jointly published an interim final rule to implement this provision. This regulation became effective on December 12, 2003. We recently reopened and extended the public comment period on the Prior Notice Interim Final Rule for an additional 60 days. Comments will be accepted through July 13, 2004. Interested parties will have had a total of 165 days to comment on the provisions. We currently intend to publish the final rule in March 2005. Since December 2003, we have been receiving approximately 150,000 notifications each week about articles of food being imported or offered for import into the U.S.

FDA and CBP worked collaboratively to ensure the new regulations promote a coordinated strategy for border protection. Thanks to this collaboration, prior notice may be submitted electronically either by licensed brokers using CBP's Automated Commercial System (ACS) or by anyone using FDA's Prior Notice System Interface. FDA's and CBP's systems are linked together. Regardless of which system a submitter uses to transmit the prior notice to FDA, the notices submitted are reviewed in the same timeframes and in accordance with the same procedures.

Based on FDA's current assessment, the timeframes in the interim final rule for submitting prior notice are the least amount of time that FDA needs to meet our statutory responsibility to receive, review, and respond to the prior notice submission. They take into account different modes of transportation. The regulations require prior notice at least two hours in advance of arrival by land via road, at least four hours in advance of arrival by air or land via rail, and at least eight hours in advance of arrival by water. The staggered prior notice submission timeframes allow FDA reviewers to expedite their review of shipments with shorter transport times without negatively affecting the review times of shipments with longer transport times.

FDA and CBP are committed to further increasing integration of our agencies' respective advance notice requirements with a goal of: (1) achieving a uniform, integrated system; (2) building on current operational procedures; and (3) implementing the law with minimal disruption to current entry practices. Toward this goal, on April 4, 2004, FDA and CBP issued a plan, "Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes." The plan de-

scribes the process by which FDA and CBP intend to increase integration and examine whether we could amend the timeframe requirements in FDA's prior notice interim final rule to be the same as those in CBP's advance electronic information rule. The plan was issued with an initial 30-day comment period, which FDA has extended for an additional 60-day period that ends July 13, 2004.

Although the interim final rules became effective December 12, 2003, FDA and CBP issued a Compliance Policy Guide that explains our intention to focus initially on educating affected firms and individuals about the new prior notice requirement while gradually phasing in enforcement of the prior notice interim final rule. This phase-in period will end August 12, 2004, at which time full enforcement will begin.

While we cannot physically inspect every shipment, it is important to note that every shipment that contains FDA-regulated products that is entered for consumption or warehouse storage through CBP's ACS is electronically reviewed by FDA's Operational and Administrative System for Import Support to determine if the shipment meets identified criteria for physical examination or sampling and analysis or warrants other review by FDA personnel. This electronic screening allows FDA to concentrate its limited inspection resources on high-risk shipments while allowing low-risk shipments to proceed into commerce.

With the new prior notice requirement, specific information mandated by the Bioterrorism Act must be submitted to FDA before the imported food arrives in the U.S. This not only allows the electronic system to review and screen the shipments for potential serious threats to health (intentional or otherwise) before food arrives in the U.S., but it also allows FDA staff to review prior notices of those products flagged by the systems as presenting the most significant risk and determine whether the shipment should be held for further investigation. FDA worked very closely with CBP in developing this screening system.

In addition, FDA has been actively working with the analysts at CBP's National Targeting Center to utilize their Automated Targeting System as an additional tool to enhance the Agency's ability to focus attention on those imported foods that may pose a serious threat to public health. We anticipate that the use of FDA's and CBP's screening systems will enable both agencies to effectively target shipments posing the greatest risk in order to further focus our border inspection efforts.

In developing the interim final rules to implement the registration and prior notice requirements, FDA carefully considered all the comments received during the public comment periods and strived to develop provisions that were consistent with the Bioterrorism Act and that achieve its objectives while minimizing the impact on trade to the extent feasible. FDA and CBP have conducted extensive domestic and foreign outreach to explain the rules to consumers and the food industry. FDA has been commended by numerous parties throughout the world for what many describe as an unprecedented level of outreach.

Administrative Detention

Section 303 of the Bioterrorism Act gives FDA new authority to administratively detain any article of food for which the Agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. This authority is self-executing and provides an added measure to ensure the safety of the nation's food supply. Section 303 also requires FDA to provide by regulation procedures for instituting on an expedited basis certain enforcement actions against perishable foods subject to a detention order. On June 4, 2004, FDA published a final rule to implement this section. The rule includes procedures for detaining an article of food, expedited procedures for detaining perishable foods, and the process for appealing a detention order.

Maintenance and Inspection of Records for Foods

Section 306 of the Bioterrorism Act authorizes FDA to have access to certain records when the Agency has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. It authorizes the Secretary to publish regulations to establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. On May 9, 2003, FDA published a proposed rule to implement this section. We have received approximately 200 comment letters that we have carefully considered. We intend to issue a final rule in the near future. When finalized, the recordkeeping regulation will enhance FDA's ability to track and contain foods that pose a threat of serious adverse health consequences or death to American consumers from accidental or deliberate contamination of food.

Authority to Commission Other Federal Officials to Conduct Inspections

Section 314 of the Bioterrorism Act authorizes the Secretary to commission other Federal officers and employees to conduct examinations and investigations. Pursuant to this new authority, FDA and CBP have signed a Memorandum of Understanding to commission CBP officers to conduct examinations on FDA's behalf at ports where FDA may not currently have staff or to augment FDA staff in the enforcement of FDA's prior notice requirements. This unprecedented FDA-CBP collaboration significantly strengthens our ability to secure the border while ensuring the movement of legitimate trade. In accordance with this new authority, FDA has already commissioned over 8,150 CBP officers. The Agency will continue to explore use of this authority with other agencies as a tool to further improve efficiencies.

Authority to Mark Articles Refused Admission into U.S.

Section 308 authorizes the Secretary to require the marking of refused food (other than food required to be destroyed). This provision is intended to prevent unsafe foods that have been refused entry into the U.S. from entering U.S. markets via the practice of "port shopping." This is a practice by which importers send goods that have been refused entry at one port to a different port in the hope of obtaining admission for the refused goods. Obviously, this practice puts American consumers at risk. Before passage of the Bioterrorism Act, FDA had published a proposed rule to require the marking of refused food. This proposal was withdrawn in light of the new and additional statutory requirements. We are considering a new rulemaking to implement Section 308.

Protection Against Adulteration of Food

Section 302 of the Bioterrorism Act contains numerous provisions intended to increase protection against adulteration of food. One of the requirements in this section is for the Secretary to give high priority to increasing the number of inspections of food offered for import. Thanks to a fiscal year 2002 supplemental appropriation, FDA received counterterrorism funds that enabled us to hire additional staff, most of whom were hired to address food safety issues, primarily at the border. With these additional employees, we have more than doubled the number of ports that have an FDA presence from 40 to 90 ports. We have increased by more than sixfold the number of food examinations at the border.

In compliance with another requirement in this section, on October 16, 2003, we submitted a report to Congress, "Testing for Rapid Detection of Adulteration of Food," about the research that is underway to develop tests and sampling methodologies to rapidly detect adulterated food. FDA has commenced more than 90 different research projects to develop tests and sampling methodologies to increase the detection of adulterated food. A number of the research projects are designed specifically to develop tests suitable for inspections of foods at ports of entry. For example, commercially available test kits are currently being analyzed for a variety of food matrices to evaluate their suitability for use in the field at ports of entry. We are in the process of preparing the second annual report on our research activities.

Also pursuant to a requirement in Section 302, HHS provided a report to Congress on assessments of the threat of the intentional adulteration of food.

CONCLUSION

In conclusion, thanks to the new authorities provided by the Bioterrorism Act along with HHS' other food safety activities, the nation's food safety system is stronger than ever before. As you might imagine, it has been a tremendous undertaking for FDA to implement the provisions in the Bioterrorism Act in such a short period of time. We are proud of our accomplishments and will continue our efforts to implement the Bioterrorism Act in an efficient and effective manner. We are thankful to Congress for these new authorities that will serve to bolster the safety of our food supply.

In addition to the new authorities provided to us in the Bioterrorism Act, I would like to briefly mention some other activities in which FDA has been involved to ensure the safety and security of our nation's food supply. We have enhanced coordination with our partners in Federal, state, and local governments, academia, and industry. To minimize the risk that food will be subject to tampering or other malicious actions, we have issued guidance for the food industry on the security measures it may take. We are also working with DHS to carry out our Sector-Specific Agency responsibilities under Homeland Security Presidential Directive 7/Critical Infrastructure Identification, Prioritization, and Protection for food other than meat, poultry, and egg products. FDA has embarked on an ambitious research agenda throughout the Agency to address potential terrorist threats. To increase laboratory surge capacity, FDA has worked closely with CDC and USDA to expand the Labora-

tory Response Network by establishing the Food Emergency Response Network. Through this aggressive and collaborative program, FDA has made significant progress in strengthening the safety and security of the nation's food supply.

Thank you for this opportunity to discuss our efforts to implement the food safety provisions of the Bioterrorism Act. I look forward to continuing to work with you and would be pleased to respond to any questions.

Mr. BILIRAKIS. Thank you, Dr. Crawford. And I did not intend to speed up your testimony there.

Ms. Sauceda.

STATEMENT OF CATHY SAUCEDA

Ms. SAUCEDA. Yes, sir. Good morning. Thank you, sir. Good morning, Mr. Chairman, other members of the subcommittee. I am Cathy Sauceda, and I am the Director of Special Enforcement with Customs and Border Protection, the Department of Homeland Security. I am pleased to be here with Dr. Crawford, Acting Commissioner of the Food and Drug Administration.

I want to thank you for this opportunity to discuss Customs and Border Protection's actions to implement the food safety provisions of the PublicHealth Security and Bioterrorism Preparedness Act of 2002, or what we call the Bioterrorism Act.

This legislation presented a significant opportunity to enhance protection of our imported food supply chain against the threat of intentional contamination and other food-related emergencies while challenging us to facilitate the movement of legitimate goods. Meeting this balance between safety and facilitation has been a top goal for Customs and Border Protection.

In my testimony today, I will first provide some background on Customs and Border Protection's responsibilities, and then describe some of the key actions that CBP has taken to implement the food safety provisions of the act and ensure that legitimate trade is facilitated.

The primary mission of Customs and Border Protection is detecting and preventing terrorists and terrorist weapons entering the United States. As the single border security agency, Customs and Border Protection has twin goals: To secure America's borders while facilitating the flow of legitimate trade and travel.

With respect to the Bioterrorism Act, CBP has worked in concert with the Food and Drug Administration to detect and intercept violator shipments by providing personnel with experience in targeting and CBP officers to perform BTA-related work in over 300 ports of entry.

Joint targeting and training in our automated targeting system and use of our automated commercial system to meet the regulatory submission requirements for the prior notice that was required under the act has been undertaken. Use of our automated broker interface as part of our automated commercial system allows the trade to meet timely prior notice requirements without having to enter prior notice data into two different systems, which would be the Food and Drug Administration's PNSI system and CBP's ACS. Using ACS also ensured that these new requirements would be less likely to disrupt the flow of trade.

As part of the joint targeting, Customs and Border Protection and FDA are collocated at CBP's National Targeting Center, where FDA has established their Prior Notice Center. A jointly developed

scoring rule set for FDA which enables them to use CBP's automated targeting system has been developed and is being continuously refined. By working together to define and determine risk, FDA can more readily identify anomalies in food importations and concentrate efforts in areas of high risk.

Cooperative agency efforts also allow CBP and FDA to perform joint targeting so goods will not be inspected twice, once for FDA and once for CBP, for terrorism.

In addition, we have worked, as Dr. Crawford says, with the FDA to commission some 8,000 Customs and Border Protection officers to take action on behalf of FDA in a 24 by 7 mode. This commissioning allows FDA to assert a 24 by 7 presence to enforce the act at all ports when FDA staffing is either limited or nonexistent. This 24 by 7 presence at all ports allowed FDA to lessen the prior notice timeframe stated in the notice of proposed rulemaking to 8 hours by vessel, 4 hours by air and rail, and 2 hours by truck, which is listed in the interim final rule.

Recognizing the impact on the trade and the possibility of having ports literally closed due to the failure to comply with this legislation, Customs and Border Protection has worked diligently with the Food and Drug Administration and independently on outreach programs both domestically and internally. We trained our Customs and Border Protection attaches, and we, independently and with FDA, went to Europe, South America, Central America, and Mexico to conduct outreach to train our customers. Special care has been taken to ensure that our immediate neighbors, Canada and Mexico, have been included in the training and operational discussions, addressing their concerns to the extent possible, while still remaining in compliance with the law.

Our efforts to ensure that legitimate trade would not be compromised led us in cooperation with FDA to apply a phased-in approach to enforcement. This phased-in approach started on December 12, the date of the implementation of the act, 2003, and is progressing through four phases that started with informed compliance and is moving toward full enforcement on August 13.

We are currently in phase three of the enforcement plan. For the first time, in phase three, shipments were refused for failure to file prior notice. Despite this, there has been very minimal disruption in the trade as our efforts in outreach have been successful. Only 2,479 shipments have been found to be not in compliance since June 4.

During the phased-in approach, we have continued our outreach in addition to jointly issuing the compliance guide explaining the four phases of increasing enforcement and possible consequences of noncompliance. As we move closer to full enforcement, we will continue to refine procedures, identify, and correct systemic or logical problems, and address legitimate trade concerns with compliance of the act. We will continue to work with FDA in improving their target ability and to coordinate timeframes with those listed in CBP's advanced electronic role.

I would like to thank you for this opportunity to discuss our efforts and implementation of the food safety provisions of the Bioterrorism Act. I looked forward to continuing to work with you, and would be pleased to respond to any questions.

[The prepared statement of Cathy Sauceda follows:]

PREPARED STATEMENT OF CATHY SAUCEDA, DIRECTOR, SPECIAL ENFORCEMENT, CUSTOMS AND BORDER PROTECTION

Good morning, Chairman Bilirakis and Members of the Subcommittee. I am Cathy Sauceda, Director of Special Enforcement, Customs and Border Protection (CBP), which is part of the Department of Homeland Security (DHS). I am pleased to be here today with Dr. Lester M. Crawford, D.V.M., PH.D., Acting Commissioner of the FDA.

Thank you for this opportunity to discuss CBP's actions to implement the food safety provisions in Title III, Subtitle A—Protection of Food Supply—included in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). This legislation presented a significant opportunity to enhance protection of our imported food supply chain against the threat of intentional contamination and other food-related emergencies, while challenging us to facilitate the movement of legitimate goods without causing undue delays and economic hardship. Meeting this balance between safety and trade has been a top priority for CBP.

In my testimony today, I will first provide some background on CBP's responsibilities. Then, I will describe the many actions taken by CBP to implement the food safety provisions of the Act and ensure the facilitation of legitimate trade.

The primary mission of Customs and Border Protection is detecting and preventing terrorists and terrorist weapons from entering the United States. As the single border security agency, CBP has twin goals: to secure America's borders while facilitating the flow of legitimate trade and travel. With respect to the Bioterrorism Act, CBP has worked in concert with FDA to detect and intercept violative shipments by providing personnel with expertise in targeting and CBP officers to perform BTA related work at more than 300 ports of entry.

Joint targeting and training in the use of our Automated Targeting System (ATS), and use of our Automated Commercial System (ACS) to meet the regulatory submission requirements for Prior Notice as required under the Act was undertaken. Use of our Automated Broker Interface (ABI), a part of ACS, allows the trade to timely meet the Prior notice requirements without having to enter Prior Notice information into two electronic systems (FDA's PNSI and CBP's ACS). Using ACS also ensured that these new requirements would be less likely to disrupt the flow of legitimate trade. We have jointly enhanced both of our systems, ACS and OASIS, the FDA automated system, to accommodate the new user requirements as required to meet the statute.

As part of the joint targeting, CBP and FDA are co-located at CBP's National Targeting Center, where FDA has established their Prior Notice Center. A jointly developed scoring rule set for FDA which enables them to use CBP's Automated Targeting System has been developed and is continuously being refined. By working together to define and determine the risk, FDA can more readily identify anomalies in food importations and concentrate resources in areas of risk. Cooperative agency efforts also allows CBP and FDA to perform joint targeting so goods will not be inspected twice—once for each agency for the purpose of prevention of terrorism.

In addition, we have worked with FDA to Commission over 8,000 CBP officers to take action on behalf of the FDA under the Act. This commissioning allows FDA to assert a 24 X 7 presence to enforce the Act at all ports, even when FDA staffing is limited or non-existent. This 24 X 7 presence at all ports allowed FDA to lessen the Prior Notice timeframes stated in the Notice of Proposed Rulemaking to 8 hours by vessel, 4 hours by air or rail and 2 hours by truck as stated in the Interim Final Rule.

Recognizing the impact on the trade and the possibility of having ports literally closed due to failure to comply with this legislation, CBP has worked diligently both with the FDA and independently on an outreach program, both domestically and internationally. We trained CBP attaches as to the requirements of the Act, which allowed them to conduct training in their respective foreign countries. These sessions supplemented additional presentations that were given by CBP to governmental and trade associations throughout Europe, Asia, and South America. Special care has been taken to ensure that our immediate neighbors, Canada and Mexico, have been included in the training and operational discussions, addressing their concerns to the extent possible while still complying with the law. Presentations have been given to various domestic trade organizations such as the Pacific Coast Counsel, who is also here to speak, and we have formed a joint task force with the National Customs and Brokers Association (NCBFAA), who are also in attendance.

Our efforts to ensure that legitimate trade would not be compromised led us, in cooperation with the FDA, to apply a "phased in" approach to enforcement. This

phased in enforcement started on December 12, 2003 (the implementation date required under the Bioterrorism Act) and is progressing through four phases that started with informed compliance and is moving towards full enforcement on August 13, 2004.

We are currently in Phase III of the enforcement plan. For the first time, shipments were refused for failure to file Prior Notice. Despite this, there has been minimal disruption in trade as our efforts in outreach programs were rewarded.

During the phased in approach we have continued our outreach, publishing pamphlets in English, Spanish and French for the traveling public, jointly issuing a Compliance Guide explaining the four phases of increasing enforcement and the possible consequences for failing to meet the requirements under the statute. In addition, we have issued an internal and public version of mitigation guidelines for the issuance of penalties.

As we move closer to full enforcement we will continue to refine procedures, identify and correct systemic or logistical problems and address legitimate trade concerns with regard to the Act. We will continue to work with the FDA in improving their targeting ability so as to coordinate its timeframes with those in CBP's Advance Electronic Rule. This will lead to more accurate targeting of possible high threat shipments, thus ensuring the safety of imported food while simultaneously not acting as a barrier to trade.

Thank you for this opportunity to discuss our efforts to implement the food safety provisions of the Bioterrorism Act. I look forward to continuing to work with you and would be pleased to respond to any questions.

Mr. BILIRAKIS. Thank you very much, Ms. Sauceda. I will start off the questioning. There is a long list of questions, and as per usual we submit them to our witnesses and then they respond in writing. So we would hope you would do that in a timely fashion.

I am just going to focus on one. Ms. Sauceda and Dr. Crawford, take us to the border—to a border. There are a number of means whereby manufacturers, researchers, plain people, ships bringing in, you know, containers, et cetera, et cetera, bring in food to this country. Take a couple of those of your choosing, and explain to us exactly what happens, sort of a step-by-step process in terms of how you coordinate with FDA. You know, the interaction—apparently both of you have indicated that the interaction of your two agencies works well, and I am very happy to hear that. We don't always get that information. But sort of take us through something like a—pick an illustration, if you will, and take us through step by step.

Ms. SAUCEDA. Speaking on our land border, which is my main area of expertise, now with the filing of prior notice, FDA becomes aware, as does Customs and Border Protection, in advance of the arrival of the shipment of the goods. If those goods are determined to be suspicious, then those goods are actually held at the border location, they are not allowed to proceed. Both FDA and CBP will become aware at the same time that these are violated goods that will be held. The determination is made jointly by Customs and Border Protection and FDA at a Customs headquarters office here in Washington where they are collocated.

Mr. BILIRAKIS. Excuse me. You know in advance that these goods are coming?

Ms. SAUCEDA. Yes.

Mr. BILIRAKIS. Might there be any instances of that type of volume where you would not know in advance?

Ms. SAUCEDA. No. Under the prior notice rule, we will have the—the only way we would not know in advance is if someone tried to make an entry without following the proper paperwork. But assuming they are in compliance, we would know in advance. Jointly, we

determine that we will inspect the goods. Jointly, we, CBP, look to see if we have a need to inspect while at the same time FDA has a need to inspect. We contact the ports of entry so that they are very aware, they are aware the goods are coming, and we—both agencies meet these goods as they arrive at the location and we do our inspections. That could also include the Customs inspections for x-rays, dogs, any other type of activity. And we both clear the goods, one examination, and then we would allow the goods to proceed. Or, if we needed to send it to some kind of a facility for examination, under the Bioterrorism Act of course it has to go to a secure facility and can't go to the owners or importers' premises. But FDA and CBP know the whole time what is happening to the goods, and we know when the goods are in compliance and when the goods are allowed to be released.

Mr. BILIRAKIS. All right. Now, under what type of instances might you be sort of suspicious at the outset and feel that a better examination is required? Would it be based on the particular organization that is bringing the goods in or their history, that sort of thing? Where they maybe have initiated from?

Ms. SAUCEDA. Prior to December 12, the actual implementation, CBP and FDA took their best and brightest targeters and all the intelligence that we had through FDA's system and through our intelligence and our system, including what we know of importers, what we know of suspicious countries, and all the types of items that go together to confirm a risk. And we put all of that into what we call a rule set. And when those criteria come up in a shipment, maybe it is a first-time importer, maybe it is—we have always had problems with bottled water from Turkey, for example. The system sees that and kicks it out and says, wait a minute, this is a shipment that perhaps we need to look at.

And then, of course, there is always human intervention; that we see something, it doesn't look right, and then we go ahead and target it for examination.

Mr. BILIRAKIS. I am sorry, Dr. Crawford. Did you have something you wanted to add?

Mr. CRAWFORD. Just that we also from time to time, as Ms. Sauceda well knows, receive tips or information that it is given to us, and we consider those also.

Mr. BILIRAKIS. All right. Now, you know, in coming in, I guess maybe we have all made mistakes from overseas trips bringing in, oh, I don't know, maybe some figs or an apple or something of that nature. And obviously, if you report that, it is confiscated. And that was done for reasons other than concerns of terrorism and what not, obviously, in those days. Has that slacked off a little bit because of more emphasis being put into homeland security, if you will?

Ms. SAUCEDA. The emphasis of just taking goods from passengers?

Mr. BILIRAKIS. Routine, yeah. The routine check for foods coming in, which was for health purposes and what not.

Ms. SAUCEDA. The Department of Agriculture is still very much involved, and they regulate many of the items that come in. The Bioterrorism Act is not concerned necessarily with personal shipments brought in by the traveler. But still, if a passenger brings

in a mango or brings in some kind of food that is prohibited by them, they would still be asked to abandon the goods or I guess return them back to the country of export.

Mr. BILIRAKIS. But your resources have not been shifted to any large degree from the one to the other, to put more emphasis on the homeland security, as far as you know?

Ms. SAUCEDA. Well, generally, in these locations the parties that are detecting this are the same parties that are clearing them from Immigration. So they are really doing multi-functions on this passenger at the same time.

Mr. BILIRAKIS. Thank you.

Dr. Crawford, anything you wanted to add?

Mr. Crawford. No. The Animal and Plant Health Inspection Service continues, and I believe their strength has actually even increased some. I do not know whether the confiscation of things like sausages and whatever that are brought in has increased or decreased. But we can communicate with them and get that for the record, if you would like.

Mr. BILIRAKIS. No, that is okay. I think you would know.

Mr. Brown to inquire.

Mr. BROWN. Dr. Crawford, the prior notice requirement took effect last December. And even though you won't be enforcing them—my understanding—enforcing the requirement for another couple of months, you I would guess have some idea after 6 months of operation as to how it is going. And I would like, if possible—I don't expect answers to this today, but if in writing you could get us some statistics on how the program is working.

Mr. CRAWFORD. We will.

Mr. BROWN. Okay. Thank you. How many shipments reach ports of entry without prior notice, how many prior notice submissions have simple clerical errors that could result in a shipment being turned back, how many are prior notice submissions complete except for the manufacturer's registration number, and how these and other numbers have changed, if folks have gotten used to the new system? If you could get us that.

Mr. CRAWFORD. Absolutely.

[The following was received for the record:]

Q: How many shipments reach ports of entry without prior notice?

A: A recent review of entry data from Customs and Border Protection's Automated Commercial System (ACS) during the week of June 27 through July 3 shows that prior notice was not submitted for 625 food items. This represents less than 0.5% of a total of 128,829 food items entered through ACS for which prior notice should have been submitted.

Q: How many prior notice submissions have simple clerical errors that could result in a shipment being turned back?

A: At the present time, we are operating in a period of enforcement discretion in which shipments are generally not being refused for failure to submit a complete and accurate prior notice. Thus, FDA has not been turning back shipments due to simple clerical errors. After this transition period, submitters will have the opportunity to correct faulty data submissions, including those resulting from clerical errors, because both the ACS and FDA's Prior Notice System Interface will not accept a submission until all required fields are completed. If, however, a shipment is refused because of inaccurate prior notice, the person may resubmit the prior notice instead of exporting the shipment.

Q: How many prior notice submissions are complete except for the manufacturer's registration number?

A: Based on a snapshot of activity in July, approximately 13% of prior notice submissions in ACS contain no registration information (i.e., name, address, and reg-

istration number associated with the article of food) and approximately 3% contain a registration number that is not on file at FDA.

Q: How have these and other numbers changed as folks have gotten used to the new system?

A: The percentage of shipments entered through ACS that contain all the required data fields has increased from 49% in January to 78% in July. We expect the completeness of the prior notice submissions to continue to improve as people gain experience with the system and as we near the period of increased enforcement.

Mr. BROWN. I want to shift gears slightly, and I know the substance of this hearing and I appreciate your being here. And I am troubled by the—and this was not really on your watch, although it is beginning to be—troubled by the increased politicization of what I think once was the finest, perhaps the finest agency in the Federal Government. And it started 2 or 3 years ago, when I remember in this subcommittee and in a meeting prior to that—and, again, this is not your fault or under your watch. But the FDA, top people at the FDA came in, and in a presentation to us about safety, about what I thought was about the FDA's major charge, safety, protecting the public, talked about their pride—in leading off their presentation, their pride in the fact that the U.S. drug industry now has a higher percentage of the world market than ever before, how we were going to together increase that. Which is a good thing, but not the charge of the FDA.

And now I am further troubled by two other more recent events. One is during the reimportation legislation the fact that the FDA actually lobbied Members of Congress—which I thought was illegal; it is certainly untoward—and then now the sort of continued scare tactic FDA is putting out to the American public that drugs from Canada are or could be potentially contaminated, as if there are new stories in the front page of the French, French and Germans and Japanese and Israelis and Canadians dropping dead on the streets from contaminated drugs. You know, we are safely importing food for Yemen and Iran and places that State Department says that clearly are more troubling places, and yet we can't seem to safely—the FDA, some of your spokespeople seem to say we can't safely import prescription drugs from Canada.

My question is that, rhetorical and otherwise.

And also, I would like—if the FDA is going to continue to say these drugs aren't safe, if you would begin to give us some names of people who have been harmed by contaminated drugs. I do know that Jeffrey Truitt, the FDA—not the FDA; sometimes I get them mixed up too often anymore—PhRMA's—I apologize for that, bit of a cheap shot, but unfortunately there seems to be more leaning that way in this agency. But PhRMA's top spokesperson, made a statement to a paper in my hometown that 15 percent of drugs coming from—this is passed through a reporter saying this. Either 15 percent of drugs imported from Canada or imported overall were counterfeit, which is the term he used, which is misleading, which I believe means not FDA approved. But nonetheless.

can—but if these statements are going to keep coming from the FDA, we would like to see real specific cases. Are there any?

Mr. CRAWFORD. We have very little in the way of adverse reactions or deaths from Canada or any other country that exports to the U.S.

Mr. BROWN. Very little, or none?

Mr. CRAWFORD. Very little. From time to time there is a reaction of some sort or another. We also have reactions from U.S. produced drugs. However, we can provide you what information we have. But as you know, we are in the business of preventing these kinds of events from taking place. And FDA is required, as you also well know, by law to go and conduct inspections at any plant that is going to be producing drugs for the U.S. market, wherever it is. So obviously we have more comfort with drugs that are produced and remain in the United States. That is sort of natural.

And I would also say that we still have the pride in FDA. I haven't—I have been at FDA four different times, but I mostly in my career have been elsewhere. But as you know and as you indicated, around the world and here in the United States this is a very respected agency. We must maintain that integrity and respect. And I appreciate your comments about that, and we will provide what we have.

Mr. BROWN. Thank you.

[The following was received for the record:]

Question (paraphrased): Is FDA aware of deaths resulting from the importation of prescription drugs?

Answer: First, we want to emphasize that FDA is unable to ensure the safety and effectiveness of drugs imported by individuals from other countries. It is FDA's goal to prevent death or serious injury from adverse reactions to marketed drugs to the greatest extent possible, and we have not waited for deaths to occur before expressing our strong concern about the importation of medications outside of the regulatory system established by Congress in the Food, Drug, and Cosmetic Act.

FDA remains concerned about the public health implications of unapproved prescription drugs obtained from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs shipped to U.S. consumers by foreign sellers that are purported to be the same as FDA-approved prescription drugs are, in fact, of unknown quality. Consumers are thus exposed to a number of potential risks, such as expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding safe use and side effects may not be available to the consumer.

These concerns are amplified by the experience with state programs that facilitate access to Canadian prescription drugs. Recent research by the state of Minnesota pointed out significant problems related to purchasing non-FDA approved pharmaceuticals from Canadian pharmacies. Minnesota State health officials observed Canadian pharmacies engaging in problematic practices during a single, voluntary, pre-announced "visit." The officials noted dozens of safety problems, such as:

1. Several pharmacies used unsupervised technicians, not trained pharmacists, to enter medication orders and to try to clarify prescription questions;
2. One pharmacy had its pharmacists review 100 new prescriptions or 300 refill prescriptions per hour, a volume so high as to make it impossible to assure safety;
3. One pharmacy failed to label its products, instead it shipped the labels unattached in the same shipping container, even to patients who received multiple medications in one shipment; and
4. Drugs requiring refrigeration were being shipped un-refrigerated with no evidence that the products would remain stable.

At least one of the Canadian pharmacies visited by Minnesota health officials dispensed many drugs that apparently were not even of Canadian origin, and many of the drugs were obtained from prescriptions that had been written and rewritten across multiple Canadian provinces. These types of systematic safety problems would generally be clear regulatory violations that would not be tolerated under the comprehensive system of Federal and state regulation of drug safety in the U.S.

Similar problems have become evident in the operation of the state of Wisconsin's Prescription Drug Resource Center. In reviewing the reports submitted by the three Canadian pharmacies linked to the Wisconsin website, the Pharmacy Society of Wisconsin has identified serious breaches of the agreements under which the pharmacies participate in the state program. The Society found that of the 765 prescriptions dispensed by the pharmacies, 316 (over 41%) violated the state agreements.

Specifically, 127 of the dispensed drugs were products not approved by FDA or available in the U.S., while 189 of the drugs were products not authorized by the state program. In six instances, the pharmacies improperly sent drugs requiring refrigeration through the mail. Additionally, one of the Canadian pharmacies advised the state that it intended to obtain drugs from a European supplier, even though that was specifically prohibited by its agreement. Responding to these reports, the Wisconsin Department of Health and Family Services sent letters to the three pharmacies on April 27, 2004 ordering them to cease these prohibited practices, however, these problems have not abated. In reaction to these reports, the executive director of the Wisconsin Pharmacy Society, the professional association representing licensed pharmacy practitioners in the state, concluded that "no one in Wisconsin has any real idea what these Canadian businesses are doing."

Significant safety issues surfaced when representatives of New Hampshire Governor Craig Benson visited the Canadian Internet pharmacy known as CanadaDrugs.com, located in Winnipeg, Manitoba. The "terms of service" for CanadaDrugs.com requires purchasers to agree that they "will not be liable for damages arising from personal injury or death" from the use of drugs sold by the pharmacy. Under this practice, the consumer has no recourse for injuries arising from the use of drugs from this shipper. Additionally, the website allows patients to send in their prescriptions by fax, when the practice is illegal under the law in New Hampshire and other states.

FDA is generally unable to quantify adverse events from imported prescription drugs for a number of reasons. First, the adverse event reporting system in the U.S. is not geared towards distinguishing between foreign or domestically obtained drugs. Second, there is a natural reluctance on the part of patients or their representatives to report adverse effects of drugs that were obtained outside of the normal, legal channels.

While FDA has not attempted to quantify the number of deaths or serious injuries resulting from imported prescription drugs, we are keenly aware of testimony provided to as many as three Congressional committees by numerous families who have suffered the loss of loved ones as a result of taking prescription medications obtained through the Internet or foreign sources.

Mr. BILIRAKIS. The Chair recognizes Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman, and I appreciate my colleague from Ohio's concerns. That is a current political and policy debate. But I know that our Oversight and Investigations Subcommittee has held hearings on that issue and I know Jim Greenwood actually has bottles labeled as if it was in the United States and stuff. And I kind of used some of that oversight investigation in my discussion of that issue that we are talking about. It is not just—it may be dilution of drug, it may be not the proper instructions, it could be again, dosage, labeling, and use and handling and other things that may not be just the empirical aspects of the drugs. So—but it is something that we need to continue to get a handle on.

I want to now follow up with a question on this prior notice stuff that—and to you, Dr. Crawford, in the information the person filing the prior notice has to supply includes shipper and manufacturing details such as manufacturer's FDA registration number. But there are many cases where this information is not available. How will manufacturers and research laboratories be able to submit prior notices to get samples of food into the United States when that information needed to file a prior notice cannot be obtained?

Mr. CRAWFORD. Well, what we have tried to do with this registration number is we have tried to link the registration provisions of the act with the prior notice provisions. And one thing that helps us a great deal in FDA is if there is a registration number. Because if the number is there and we can check very quickly to see if it is valid, electronically, then we know that they are registered. If

the number—if we didn't use the numbering system or numerical system, we would be—we would not have improved our surveillance at all because we would be back into the old days of trying to look at what the address in France, Germany, or wherever it was, and wondering if they were people that we didn't need to check. And so we would be detaining shipments that we did not need to detain, and it would be time consuming and we might miss something because of that. So this gives us efficiency and it also links these two provisions together. But there are——

Mr. SHIMKUS. We understand that. I mean, that is the presupposition of the question. So if they don't, then what are we going to do about it? Or, I mean, are they not going to be able to submit?

Mr. CRAWFORD. There are people that, there is like a gray market and there is also a market where people buy substances from manufacturers and then ship them without the permission of the manufacturer. And there is always this kind of trade going on. We have been working with CBP to try to improve this situation and make sure that we don't impede trade because of this particular kind of circumstance. There are also goods that are returned to the U.S. after they leave the U.S., and some of these are foods that are sold at Costco and stuff like that. So we may need to come back to the Congress with some suggestions of our experience at some point and say to you that maybe we need some help.

Mr. SHIMKUS. Let me briefly ask one more. There are facilities exempted in the act and in the FDA's regulation from registration. Should other types of facilities be exempted also?

Mr. CRAWFORD. Well, I think we would like to have a little more experience with that. I think that Congress got it right. However, in the practicality of policing the borders we may come up with some new categories. And also, as you know, trade changes all the time. Since 1994 and the World Trade Organization treaty, food trade has increased about fivefold in the United States, as I believe the chairman mentioned. So over the years it could be that niches develop that aren't covered and don't need to be covered, and then we can exempt them. We are open-minded about that.

Mr. SHIMKUS. I think that the testimony is there is estimated 400,000 facilities that need to be registered with the agency. Have they in fact been registered. Why are so many facilities not yet in compliance?

Mr. CRAWFORD. We estimated, based on the best information we had, that there would be around 400,000 that needed to register. Not that many have registered so far. So it could be that we overestimated the number of facilities. However, we are continuing on our outreach program to help them register, and we have a hotline that is open to help them.

Mr. SHIMKUS. Thank you.

Mr. Chairman, I think this speaks to the importance of this hearing, and probably a need to return in the appropriate time when some of these questions can be answered. I yield back.

Mr. BILIRAKIS. Well, we hear the bells ringing. We have got a problem here. I was hoping we could finish up with this panel before 10:30, because I know Dr. Crawford—again, he is willing to stay if need be.

Bart, you have 8 minutes, according to the rules. Gene, you have 5 minutes. If you plan to take virtually all of the time, I guess the only thing I can do is break.

Mr. STUPAK. I would probably take all of my time.

Mr. BILIRAKIS. Okay. Well, we have more than one vote, apparently. So, forgive me, but I guess that is the only thing we can do. All right. We will break until, I don't know what we are talking about here, probably about 15, 20 minutes. Okay. Assuming it is only two votes at the most.

[Brief recess.]

Mr. BILIRAKIS. Is Ms. Capps prepared to inquire at this point in time?

Mrs. CAPPS. Thank you, Mr. Chairman. And I apologize, I was on the floor during your testimony. But I do have some questions that I was hoping I would could ask of FDA.

On page 9 of your testimony, you state that with the new prior notice requirement, specific information mandated by the Bioterrorism Act must be submitted to FDA before the imported food arrives in the United States.

I wonder if you could be—list some specific information to which you refer and provide citations to this statute.

Mr. CRAWFORD. Yes. I can do that for the record; but let me just summarize what we are looking for. That is, we are looking to see whether or not they have registered with FDA, and that would be manifest by a registration number. And then we are also matching them with CBP toward a list to see whether or not we have any information about the firm that might cause us to be suspicious about it. And also, we are very interested, as you would know, of the origin of the shipment. And we need also at that point to know where it came from—not just where it was manufactured, but where it came from and where it is going. It is called "one up and one back" rule.

And then my experience in working with FDA off and on for 30 years is that if they don't know where it came from, they don't know where it is going, then we don't need it.

Mrs. CAPPS. And this is an ongoing and well understood policy?

Mr. CRAWFORD. It is, yes, and we maintain a hotline for shippers 24 hours a day, 7 days a week, which is called a prior notice center. So they are well aware of how to communicate with us. And it is working, I think, very well indeed.

Mrs. CAPPS. So you feel that there is great both knowledge of the regulations and compliance with it?

Mr. CRAWFORD. Yes.

Mrs. CAPPS. It is a smooth—it hasn't really—9/11 and all of these implementations have not really delayed or caused serious problems?

Mr. CRAWFORD. Correct. What some people were worried about was long backups at the border, and we have not had that, absolutely have not had that.

Mrs. CAPPS. That is good. Whether or not there was a 9/11, that is good information to have.

If I could turn to section 307 of the act, which establishes the prior notice of the—and in doing so lists several items that the notice must contain. It doesn't mention or require that the registra-

tion numbers specified in section 305 for food facilities be required in the prior notification. And I will go on and then you can comment any way you would like. It appears to be the case that the interim final rule on prior notification requires a registration number because FDA believes it is helpful to achieve the purpose of the act and it is not being required because the statute says so. Am I understanding this correctly?

Mr. CRAWFORD. You are correct. That statute does not call for a registration number. We believe it—well, we know that it is useful to us.

Mrs. CAPPS. A registration number?

Mr. CRAWFORD. Yes, because that is really the only way we know that they have registered, unless we take their address and so forth and check it, and that might cause backups at the border. So we think it is an efficient way to do business, but it is not called for by the statute.

Mrs. CAPPS. So do you think it should be?

Mr. CRAWFORD. I think it is a tool that we cannot do without and do our job, and that is up for the Congress to decide.

Mrs. CAPPS. Well, that is why this hearing is going on, and I certainly would hope that you feel that that is a good reason for you to be here so that you can let us know. How do you know something works until you try it for a while?

Mr. CRAWFORD. Absolutely.

Mrs. CAPPS. And this is one area, it wouldn't be hard to require it, right?

Mr. CRAWFORD. No, it would not be.

Mrs. CAPPS. So that is one thing I am taking note of.

Mr. CRAWFORD. Thank you.

Mrs. CAPPS. Maybe just try to do one more since I have another minute.

In some of the testimony that will be presented for the second panel, there is an indication that FDA needs to step up—you need to step up your education efforts to be sure that industry properly understands what constitutes prior notification. It didn't sound like that was a need from you. But if we are going to be hearing that in the second panel, I would like to give you a chance to respond. Some of this must wait for a final rule, clearly, but can you tell us what you are doing now and what you plan to do when this rule is final? In other words, what can we anticipate?

Thank you.

Mr. CRAWFORD. I have had the privilege of reading some of that testimony, and assuming they stick to the testimony, I think I can answer that.

Mrs. CAPPS. Thank you.

Mr. CRAWFORD. I believe that what the witnesses are probably calling for is a continuing education program, an outreach program. Prior to the implementation of the rule, we did considerable outreach in the United States. But also we visited or had group regional meetings with 80 countries, and these are the primary ones that ship food to the U.S. Those were done outside of this country and also here. But the temptation is, is that once it starts you might not need to do that again. But that is wrong. FDA needs to continue its outreach and its education programs on an ongoing

basis. In the past, as you know, with some of our food safety rules like HACCP and the low acid canned foods and some things like that, we have at some point delegated with FDA oversight to third-party organizations to continue that. And I think that is now beginning. We use organizations like the Food and Drug Institute, National Food Processors Association, and others, that we work carefully with. And I think, I think we must be held accountable for continuing that. Whoever is sitting in my position, it ought to continue.

Mrs. CAPPS. One quick thing. Is this a burden? I mean, do you have staff for it? We all get a little lax sometimes, and we think we have done our job and we move on and we find that there are new players, and just as you have mentioned.

Mr. CRAWFORD. We can do it. As you know, we have an exquisitely balanced set of resources, is the nicest way to put it. But we are committed to doing this, and we can get it done.

Mrs. CAPPS. Thank you.

Mr. CRAWFORD. Thank you.

Mr. BILIRAKIS. Mr. Stupak for 8 minutes.

Mr. STUPAK. Thank you, Mr. Chairman.

Dr. Crawford, since you have to go, let me try to get a couple questions in before you have to leave here. Does the FDA have a goal for the percentage of the import shipments it would like to inspect?

Mr. CRAWFORD. Actually, that is based on a risk assessment. We have this computer program and we also have our people on the ground now, and we have also commissioned CBP people. So there is no percentage that we are striving toward. Some shipments we are going to need to inspect more than others. It is based on what our concerns are. Others would be less. So there is no percentage that we are shooting for.

Mr. STUPAK. Well, what is the actual percentage of inspections you are doing then?

Mr. CRAWFORD. Of food shipments?

Mr. STUPAK. Yes, sir.

Mr. CRAWFORD. Around 2 percent.

Mr. STUPAK. So you are doing 2 percent. So is your goal 4 percent? 10 percent?

Mr. CRAWFORD. We have no goal. It is based on the risk. And if we believe that on a given day everything needs to be inspected, then that would be 100 percent. And some days——

Mr. STUPAK. How are you going to do it? If you are doing 2 percent, and if some day your goal is 100 percent, how are you going to do it? You are going to use people all over the place, which is impossible to do.

Mr. CRAWFORD. We just slow them down, and we comb through and we get extra help. We can—as you know, we have commissioned CBP, and we also can commission other agencies.

Mr. STUPAK. If you just slow them down, why don't you slow them down now and do more than 2 percent of actual inspections?

Mr. CRAWFORD. Because, based on risk assessments, we don't believe that it is indicated that we do that. We don't think the risk is there to do 100 percent.

Mr. STUPAK. Risk from terrorism, or risk from human health?

Mr. CRAWFORD. Both. We treat them the same. We believe that if we are extremely concerned about terrorism, we will do a better job of general food safety. And I think that has turned out to be the case. And the bill, the act has helped us with that to focus ourselves. So I think the two go hand in hand.

Mr. STUPAK. Well, let us go to the act for a minute. Because long-term, the rules, the final rules on facility registration and prior notice narrow the definition of food to exclude food contact materials such as packaging. While the legal analysis is interesting, it omits any consideration, much less discussion, of the basic purpose of the Bioterrorism Act, which is to protect Americans from intentional food contamination. Acts of terrorism certainly could be carried out via tampering with the food contact materials which in turn contaminate food that is consumed.

Given the act that the act is designed to address, can you comment on whether you may reconsider this decision and go back to the definition contained in the proposed regulation? My question is not whether or not you can support a definition, whether you should adopt it and given the purposes of the act.

Mr. CRAWFORD. Well, we can provide for the record our experiences and also an analysis of what we think the risks are from food packaging materials. And——

Mr. STUPAK. But isn't your experience basically none, zip, zilch? You haven't had that concern until after 9/11. Are you trying to tell me you have had material contact problems since 9/11?

Mr. CRAWFORD. No.

Mr. STUPAK. And you didn't have any prior to?

Mr. CRAWFORD. No. We have had material contact problems since FDA started.

Mr. STUPAK. How much is that?

Mr. CRAWFORD. The relative risk is very, very small. We can give you an analysis based on decade by decade, something like that. But it is very small indeed.

Mr. STUPAK. Well, when you look at a shipment, do you look for pesticide use?

Mr. CRAWFORD. If there is a country that has a history of pesticide concern.

Mr. STUPAK. Let's say Mexico.

Mr. CRAWFORD. We do a sampling of product that comes in from Mexico on a random basis to check for pesticides.

Mr. STUPAK. Do you hold that vehicle there then until that inspection is done?

Mr. CRAWFORD. No, we do not. We let them go.

Mr. STUPAK. You let them go. Then how do you recall them then?

Mr. CRAWFORD. We have a record now, thanks to the Bioterrorism Act, of where the product is going. We also have it identified so we can issue a recall after the fact.

Mr. STUPAK. When a shipment comes in, when a shipment comes in and they say—and correct me if I am wrong. But if it is coming up from Mexico and they are sending a number of trucks up, do you inspect every one of those trucks containing that shipment?

Mr. CRAWFORD. We do not.

Mr. STUPAK. And if there are six trucks, you might check one out of six?

Mr. CRAWFORD. It could be that many. Yeah. It depends on what the risk analysis shows, I mean, what our concerns are at that present time. We may check all six of them if we have reason to do so.

Mr. STUPAK. See, my concern, in Michigan we had the outbreak there in 1997, just strawberries found to have 18.4 percent violation of illegal level of pesticides. If you are only checking 2 percent, and we know strawberries have about 18 percent, we are not catching very many.

Mr. CRAWFORD. Well, I think using the Bioterrorism Act and making it work, we are going to get better and better at that because we will know better about what we are doing. The key to finding this is not, in my view, the percentage of tests that you do, but the wisdom of the tests that you pull off. I mean, you have to know what you are doing, and you can't test safety into the food. But if you believe that the food is contaminated, you should hold it up and test it and take whatever action you need to take. Like, for instance, the green onions that we just picked up from Mexico.

Mr. STUPAK. Well, my concern, when you take a look at FDA inspections, domestic and imports, have steadily decreased. From 1981, you had 21,000 inspections. By 1996, you are down to 5,000. And you are telling me you are at 2,000 now. If those inspections continue to go down but the threat level is up, you have changed the definition that we had in the Bioterrorism Act and you made it narrower, and you are telling me you are doing 2 percent but you can't give me what an ideal goal is, that is based upon threat assessment. I guess I am really skeptical that anything is going to change here.

Mr. CRAWFORD. Well, the number of inspections actually is 12,000 now, and—but inspections again are not the way to do it. For example, with the cantaloupe situation that you are aware of, we decided that—you know, testing is not the only thing we have at hand. But in the event of an outbreak, it is not the thing we use. What we do is we require the detention without physical examination. For example, every load of cantaloupes that came in were detained. And we are doing something similar now with onions because we are back in the onion season from Mexico, and that is like a 100 percent hold and evaluate.

Mr. STUPAK. So this inspection, the quality of it would depend upon what your inspectors feel may be the threat at the time.

Mr. CRAWFORD. The totality of what we have to use, including laboratory analysis, testing and so forth.

Mr. STUPAK. Let me go to Ms. Sauceda. You peaked my interest when you said you are using experienced people. My concern is, before you all merged together when they had the big thing, Immigration and Border Patrol and others and Customs, there is a thing called—other than full-time employees. And these employees have some—at least 5 years, some as much as 20 years working the border are being forced to compete with permanent full-time CBP officer positions. Shouldn't these people who have a lot of experience on a border be given priority or preferential consideration for permanent positions in your Agency?

Ms. SAUCEDA. Sir, I don't have an answer for you at this time, but I would like to answer your question for the record.

Mr. STUPAK. Let me ask you this then, last year, right around labor day, you claim you ran out of money so you laid people off at the ports. My State of Michigan, which borders Canada, Port Huron, Detroit, Sault St. Marie, were all laid off. What happens then to the inspections if you are laying people off because you run out of money before the end of the fiscal year?

Mr. BILIRAKIS. Very brief answer, although it is a very significant question.

Ms. SAUCEDA. Sir, I will have to answer that question for the record.

Mr. BILIRAKIS. Without objection, you will submit that information.

Mr. Green, Dr. Crawford has to be gone by 11, to inquire for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman.

I would like to ask my full statement be placed into the record.

This question is for either witness. I have a district in Houston and, in my opening statement, talked about how I have both the Port of Houston and the Intercontinental Airport. And we have both air cargo and a big container port.

And I know Congressman Stupak found out about 2 percent of the imports are being inspected. That is basically close to what our percentage is for containers. It is for general cargo. And I have been there with my Border Patrol agents or formerly Customs agents before. And the food safety imports are a concern, and I know the statistics.

Who performs these inspections for the Border Patrol and Customs? Is it actually Customs and Border Patrol agents that perform the food safety inspections on the docks?

Ms. SAUCEDA. The actual personnel in many cases that are located at the borders are CBP personnel which now include the legacy Agriculture persons and legacy Customs personnel. And I certainly don't want to misspeak here, but some 90 ports of entry, there are additional Food and Drug representatives co-located. So it is a very joint effort.

As far as inspections are conducted for the Bioterrorism Act, part of the commissioning we have done is cross-training on FDA, sampling, examination, invoice detections and anomalies where we can inspect for FDA where they are not located. So we do have a coordinated effort. But the principal party at the border location is the combined unit of CBP officers, which constitutes the legacy Immigration and the legacy CBP.

Mr. GREEN. Legacy USDA officers, I guess, for food inspection?

Ms. SAUCEDA. That is legacy Agriculture.

Mr. GREEN. Dr. Crawford, do you have anything else to add to that?

Mr. CRAWFORD. I do not.

Mr. GREEN. Ms. Sauceda , we have been contacted by a number of the former USDA workers at the Port of Houston who have been moved to DHS and specifically Customs. And while port security is certainly part of their job, these workers have been trained specifically in plant, animal and food safety, and yet they claim they are being asked to carry weapons and engage in port security, which they haven't been trained for.

And it is unusual because, typically, every Texan wants to carry a gun anyway, particularly legally. But there is a problem. I am concerned that our ports may be secured by these folks that, again, they are the legacy USDA employees without the proper training for the protection, like carrying a firearm. And second, these workers, if they are being diverted sometimes, because I know in earlier days under INS, oftentimes the naturalization side would lose folks because they had to do the Border Patrol issue and not Customs at that time. And I understand the need for cross-training.

I just want to make sure, one, they are trained—USDA legacy officers are trained. But also, would they be diverted from food safety inspections to do, you know, for example, our container cargo that may not be food-inspection related? And if you could comment on those developments.

Ms. SAUCEDA. Sir, I do know we have extensive training undergoing, being undertaken. We have training for the new agriculture inspector position and the one-face-at-the-border training, which includes all of the cross-training. I am not an expert in that area, so I will make sure we get an answer for you for the record.

Mr. GREEN. Other question we have, industry has expressed concerns about prior notice system and the different requirements imposed by FDA and Customs. And while we understand that it always takes time to iron out the details when you have a new process that we have gone into the last couple of years, that enforcement date is rapidly approaching. Can you talk about the steps you have taken to harmonize the two prior notice systems as compared to—you know, it would have to be completed by August, I believe. I know it is both agencies.

Ms. SAUCEDA. One of the most significant things that did happen was between the proposed rule or the notice of proposed rulemaking and the interim rule, where the timeframes went from noon the day before the date of arrival in the February rule to 8 hours for vessel, 4 hours for air and rail and 2 hours for truck. FDA published—and I am not certain of the exact date, I believe it was in March—that discussed that we will be analyzing the timeframes to try to be consistent with the tradeout timeframes for us, which is 24 hours by vessel, 4 by air, 2 by rail and 1 by truck. And we will begin that analysis once we get a complete handle of the compliance of the act, which will begin on August 13.

So I believe we fully anticipate FDA beginning August 13 trying to reduce the timeframes to the extent possible while allowing FDA to complete their mission of being able to stop violative shipments.

Mr. CRAWFORD. We would share that analysis with the committee and give a staff briefing if you would like.

Mr. GREEN. I think that would be helpful. I know my time is over, and I have other questions, and we will submit those.

Mr. BILIRAKIS. I would say to the Members of the panel, we have talked about possibly holding a gathering with these good people, not a formal hearing, but sitting down around a table where we could accomplish a lot more in a more informal way.

Dr. Crawford and Ms. Sauceda , thank you very much for being here today. I am sorry with what our schedules are like here, just kind of terrible, but not a good way to operate, but thank you very

much. We appreciate it. And please respond to the questions that we have sent to you.

As the next panel comes forward I want to take this opportunity to recognize a very important member of my staff, and that is Jeremy Allen. I am sure that all of you know that Jeremy is my health policy coordinator on the Energy and Commerce Committee. He is leaving my office next week. That is something that is one of the hazards up here. I guess the Energy and Commerce Committee is a breeding ground or certainly a training ground for people to better themselves downtown.

But I would like to take a moment to thank him for his extraordinary work, both for me and for the committee. He has worked for me off and on for the past 5 years. And during that time, he has been instrumental in passing historic legislation such as the Children's Health Act, the Organ Donation and Recovery Improvement Act and, especially, more recently the Medicare Prescription Drug Improvement Modernization Act. These are better laws because of Jeremy's hard work.

I wish him all the best in his future endeavors, including his wedding next month, and I know that he will be a great success because he is hard-working, diligent, extremely intelligent and really a fine, nice person.

So Jeremy, while your success is clearly my loss and this committee's loss, we all wish you good luck. And we will miss you.

Thank you for joining us in that.

The second panel consists of Mr. John Cady, President and CEO of National Food Processors Association; Mr. Roger Clarke, Williams and Clarke Company; Mr. David French, Senior Vice President, Government Relations, for the International Foodservice Distributors; Ms. Susan M. Stout, Vice President of Federal Affairs, Grocery Manufacturers of America; and Mr. Dick Saunders, Program Manager, Office of Dairy and Foods, VA Department of Agriculture and Consumer Services—Virginia Department of Agriculture and Consumer services.

Welcome.

As I am sure many of you know—most of you, if not all of you—your written statement is a part of the record. We will set the clock to 5 minutes, and, hopefully, you will be able to stay within that timeframe.

STATEMENTS OF JOHN R. CADY, PRESIDENT AND CEO, NATIONAL FOOD PROCESSORS ASSOCIATION; ROGER CLARKE, WILLIAMS AND CLARKE COMPANY; DAVID FRENCH, SENIOR VICE PRESIDENT, GOVERNMENT RELATIONS, INTERNATIONAL FOODSERVICE DISTRIBUTORS ASSOCIATION; SUSAN M. STOUT, VICE PRESIDENT OF FEDERAL AFFAIRS, GROCERY MANUFACTURERS OF AMERICA; AND R. DOUGLAS SAUNDERS, CHAIR, ASSOCIATION OF FOOD AND DRUG OFFICIALS (AFDO) FOOD SECURITY TASK FORCE, ACCOMPANIED BY BETSY WOODWARD, SPECIAL ADVISOR TO THE AFDO BOARD OF DIRECTORS

Mr. CADY. Thank you, Mr. Chairman.

My name is John Cady, and I am President and Chief Executive Officer of the National Food Processors Association. We serve as

the $500-billion food and beverage industry's voice on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs.

We supported the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. And to assure broad industry input on FDA regulatory proposals, we have provided comments to the Food and Drug Administration on behalf of our 375 member companies as well as leading the food industry's coalition in Bioterrorism Act regulations. FDA has adopted a number of the industry's recommendations, so my comments today focus on remaining industry concerns about FDA's rules for registration of food facilities, prior notice of imported food shipments and the establishment, maintenance and availability of records.

FDA has reported that about half of approximately 400,000 domestic and foreign facilities subject to the registration requirement have registered. This calls for more outreach in the form of guidelines and clarifications from FDA to educate the regulated industry about the registration requirements. While FDA has clarified that certain facilities are exempt from registration, such as private residences that hold food for distribution to consumers, we believe additional facility exemptions are warranted, including facilities that hold food as an incidental part of their businesses.

FDA's December 2003 Compliance Policy Guide allows that, under limited circumstances, unregistered facilities will have the opportunity to come into compliance before enforcement action is taken. This worthwhile enforcement policy fosters industry awareness and compliance with the registration requirement and should be maintained until greater overall compliance is achieved.

The major problem posed by FDA's interim final rules for prior notice of imported food shipments concerns the inability of industry to import research and development samples into the United States. Small quantities of food products are frequently purchased at retail and foreign countries to evaluate against comparable U.S. products or to determine the potential for producing a similar product in the United States. Under the rule, these research and development samples will not be allowed into the United States because the purchaser has no practical way of securing the registration number of the foreign manufacturing facility, which FDA requires in the prior notice. This is a requirement, by the way, that is not mandated in the Bioterrorism Act.

This places U.S. companies at a competitive disadvantage and encourages the relocation of research and development activities to Canada, for example, where imported samples are not restricted. NFPA urges FDA to just require the name and address of the foreign manufacturer on the prior notice as in the case when individuals in foreign countries send purchased products to individuals, not companies, in the United States.

Another issue is the fact that FDA and Customs' prior notice requirements differ. Full enforcement of FDA's prior notice requirements will begin in mid-August this year before FDA and Customs' requirements are harmonized. We have asked FDA and Customs to accelerate these harmonization efforts.

While FDA's final rule on records has not been issued, I want to highlight some issues raised in our comments on the proposed rule.

The proposed rule requires detailed information for each lot of production made at the company. FDA does not define a production lot. However, one definition is, all the products marked with the same unique code which may reflect the time and place of production and character of the food. The size and composition of production lots vary based on particular processes, operations and needs of each food company. While lot coding is widely used by the industry, it is not mandated for all products.

Our concern is that FDA's proposed lot-level recordkeeping poses serious technical and operational problems for collecting, maintaining and tracking the detailed information FDA is seeking. For example, as products are distributed, it is not possible, in many instances, to keep track of exact lot codes of the products that go to an individual store or to customers. Once in the distribution system, it cannot be guaranteed that a given lot of production will stay together or even the shipments of like food products will be from the same production lot. Also, the ability to precisely identify the sources of each ingredient that go into a given lot cannot be guaranteed.

It is our understanding that retail inventory and stocking records do not rely on production lot codes. Today, product recalls normally involve removal of all potential affected products rather than selective removal based on product lot codes. NFPA has urged FDA to abandon the requirement for lot-level information and records.

As FDA has acknowledged, the Agency understands that companies may only be able to identify a subset of all possible ingredient sources rather than a specific source. This FDA acknowledgment embodied in the proposed regulation should become a requirement and be applied to all ingredients and products. FDA's proposal would also require companies to produce documentation to identify the sources and recipients of food ingredients of products within 4 hours of an FDA request during a work week and within 8 hours of a request on weekends or holidays.

NFPA has suggested that FDA's review and interpretation of documentation should not be the criteria for taking needed action to address a terrorism incident. We have suggested that 24 hours is a more appropriate timeframe for producing documentation. Rather it is the immediate action by FDA on the incident that should occur. The paper review can come later.

In conclusion, I want to acknowledge FDA's efforts in seeking the industry's input in developing these regulations and the Agency's willingness to incorporate suggestions to strengthen and improve the new requirements.

However, as an industry, we do have the concerns that I have covered today. There is the need for FDA to address these issues in a timely way in order to achieve industry and FDA's common goal of reaching full compliance as soon as possible.

Thank you, sir for the opportunity to comment on this important subject.

[The prepared statement of John R. Cady follows:]

PREPARED STATEMENT OF JOHN R. CADY, PRESIDENT AND CEO, NATIONAL FOOD PROCESSORS ASSOCIATION

Mr. Chairman, my name is John Cady, and I am President and Chief Executive Officer of the National Food Processors Association. NFPA is the largest trade asso-

ciation representing the food and beverage industry in the United States and worldwide, serving as the industry's voice on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs.

NFPA supported the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) and has participated in the development of implementing regulations by providing comments to the Food and Drug Administration (FDA) on behalf of our member companies as well as by leading the food industry's coalition on the Bioterrorism Act regulations to assure broad industry input on FDA's regulatory proposals. FDA has responded to many of the recommendations from industry to make the implementing regulations more effective and workable for industry compliance. For example, in the interim final rule for prior notice of imported foods, FDA decreased the times during which a prior notice can be filed to better reflect current business practices and to better harmonize FDA requirements with those of U.S. Customs and Border Protection (CBP). FDA has also committed to determine if closer harmonization with CBP's prior notice requirements is possible. In the facility registration interim final rule, FDA reduced the amount of mandatory information that must be provided so that emphasis is placed on collecting information most relevant to meeting the provisions of the Bioterrorism Act and reducing the need for updating information that would be of minimal benefit.

The remainder of my comments today focus on remaining industry concerns about FDA's implementation of the Bioterrorism Act's provisions for the registration of food facilities; prior notice of imported food shipments; and the establishment, maintenance and availability of records.

Registration of Food Facilities

FDA estimates that there are approximately 400,000 domestic and foreign facilities subject to the registration requirement. FDA's latest compliance report on registration, however, indicates that only about 200,000 facilities have registered. While FDA may have over estimated the number of facilities that are subject to the registration requirement, a large number of facilities and companies may be unaware that they must register with FDA. More effort is needed to inform the regulated industry of the registration requirements, including additional guidance from FDA on what facilities do not need to register. FDA's current approach to clarifying facility registration requirements includes posting on their web site responses to questions raised by industry. NFPA has asked, for example, about the need to register facilities that hold food as an incidental part of their business, such as facilities that hold food for stocking on-site vending machines or facilities dedicated to consumer testing of food products. While FDA has provided guidance exempting certain facilities from registration, such as private residences that hold food for subsequent distribution to consumers, we believe additional exemptions are warranted. FDA's guidance and interpretation of the rule has been slow in coming and needs to be provided in a more timely manner to facilitate proper industry response.

FDA issued a compliance policy guide for facility registration in December 2003 that under limited circumstances gives regulated facilities that have not registered the opportunity to come into compliance before enforcement action is taken. This enforcement approach fosters industry awareness of and compliance with the requirement to register. The existing enforcement policy should remain in effect until it is clear that the majority of the regulated facilities are in compliance.

Prior Notice of Imported Food Shipments

The major problem posed by FDA's interim final rule for prior notice of imported food shipments concerns the inability of industry to import research and development samples.

Our members have informed us that small quantities of food products are frequently purchased at retail in foreign countries to evaluate against comparable U.S. products or to determine the potential for producing a similar product in the United States. For these research and development samples, the U.S. manufacturer has no practical way of securing the registration number of the facility in which the products were produced. However, under FDA's rule the registration number of the facility at which a product is produced must be included in the prior notice to bring the product into the country, a requirement that is not mandated in the Bioterrorism Act. Without an alternative means of identifying the manufacturer of the foreign product, research and development samples will be denied entry to the United States, thus eliminating what our members indicate is a valuable tool for evaluating U.S. products and new product development. This places U.S. companies at a com-

petitive disadvantage and encourages the relocation of research and development activities to Canada, for example, where import of samples is not restricted.

Also, FDA and CBP prior notice requirements are not the same. As I noted previously, FDA did change the minimum time during which a prior notice must be filed and efforts are underway to determine if the FDA and CBP prior notice requirements can be more closely aligned. However, FDA and CBP have indicated that full enforcement of FDA's prior notice requirements will begin in mid-August of this year, before prior notice requirements are harmonized. Also, CBP programs, which allow approved low risk carriers and manufacturers facilitated entry into the United States, will not be available for shipments that consist of or include food. In other words, by mid-August, a single, harmonized federal system for providing prior notice for imports of food will not be in place. Any food imported into the United States will be held at the border until a prior notice is provided that meets FDA's requirements, even if CBP requirements have been satisfied. FDA and CBP are urged to accelerate harmonization efforts and to move as quickly as possible to a single prior notice system.

Establishment, Maintenance and Availability of Records

While FDA's final rule for the establishment and maintenance of records has not been issued, I want to highlight key issues raised in NFPA's comments on the proposed rule. FDA proposed allowing existing documentation to be used to satisfy the records requirements, if the required information is provided. NFPA agrees with this approach, which takes advantage of existing record keeping systems.

The proposed rule would require companies to have information describing products and identifying sources of ingredients and recipients of products available for each lot of product with the caveat that this level of detailed information would be required where feasible. FDA has indicated that its interpretation of "where feasible" will essentially mean that all packaged food processors would be required to have detailed information on ingredient sources and product recipients for each lot of production. While FDA does not define what it considers to be a lot of production, we assume this means each set of product that has the same identification code or was produced during a given time period. Due to the nature of product distribution, particularly direct store delivery, this requirement would be either impractical or extremely costly to meet. As products are distributed, it is not possible in many instances to keep track of the exact lot codes of the products that go to individual stores or customers using existing records. One NFPA member indicated that to keep lot level information would potentially cost millions of dollars for them alone. Equally significant is the fact that lot level information would likely be immaterial in the event product needed to be removed from the market. At retail, it is our understanding that inventory records are not kept based on the lot code of the products. Similarly, product recalls normally involve removal of all potentially affected products, rather than selected removal based on lot codes. NFPA has urged FDA to abandon the requirement that companies maintain all required information at the lot level and to require information to be available on the sources and recipients of ingredients or products at the most precise level practicable for the particular food production in question. For example, for certain ingredients or products, such as bulk flour or juice, FDA acknowledges that a company may only be able to identify a subset of all possible sources rather than the precise suppliers or sources. This degree of flexibility should be allowed for all ingredients and products.

FDA's proposal would also require companies to produce documentation to identify the sources and recipients of food ingredients or products within four hours of an FDA request during the workweek and within eight hours of an FDA request on weekends or holidays. If the most significant need, as FDA indicates in its proposal, is access to information to identify the immediate previous sources and subsequent recipients of products and ingredients, then producing records under the deadlines specified should not be the priority. NFPA has suggested that FDA rely on the most readily available information from the companies involved, which may include information from knowledgeable company staff. FDA review and interpretation of documentation should not be a condition of taking needed action to address a terrorism incident. NFPA has suggested 24 hours is a more appropriate time period for producing documentation.

Conclusion

In conclusion, I want to acknowledge FDA's efforts in seeking industry's input in developing these regulations and the Agency's willingness to incorporate suggestions to strengthen and improve the new requirements and to ensure that they are both effective and achievable in meeting the objectives of the Bioterrorism Act. Thank you for the opportunity to comment on this very important issue.

Mr. BILIRAKIS. Thank you, sir.

Is someone in here from FDA taking notes? So you are being heard, Mr. Cady.

Mr. Clarke.

STATEMENT OF ROGER CLARKE

Mr. CLARKE. Mr. Chairman, I would like to thank yourself and the committee for the opportunity to address this body.

And I represent multiple associations, mainly the Customs Brokers Associations, both regional and national. The Customs Brokers, as a little bit of background, is probably the front line in the Bioterrorism Act as far as transmitting data into the systems. 80 percent of all data being transmitted will be done by Customs brokers at the Customs and Border Protection Automated Commercial System Automated Broker Interface.

Basically, we are the ones who are dealing with the actual information and getting it into the Agency. The requirements under Section 307 of the Bioterrorism Act, prior notice, has been expanded by the Agency to include vast amounts of data to be transmitted far beyond the seven data elements that are required by the bill itself.

Customs and Border Protection and Food and Drug have done outreach programs to the commerce and to the trade in the overall aspect of the bill itself, but they have been, we feel, a little bit negligent in the area of specific training in the details of the prior notice functions. As a good example, to give a timeframe of what amount of data is being transmitted on a simple shipment that I deal with, the requirements to transmit the data to Food and Drug required 934 separate transmissions for one imported shipment. And part of that is because of the convoluted amount of data that is required by Food and Drug.

A good example: You have a shipment of tuna coming in. Food and Drug requires it broken out by specific size of tuna, even though that product is from the same manufacturer, the same product. Again, it requires separate transmissions based on the size of the container. We do not feel that as a security issue of protecting the public health on a prior notice basis would require that level of detail. Customs and Border Protection is reviewing every single shipment that is coming into the country.

Under the Container Security Initiative, 24-hour prior to loading of any cargo coming into the United States, that data is transmitted into Customs and Border Protection. We feel Food and Drug could utilize that information in supplement to the prior notice.

We also feel that prior notice could be linked to the entry process versus the arrival process. The Law Registry refers to importation into the United States. Many of the unique problems encountered in the operational side of the bill or the prior notice interim rules relates to the timing of the actual arrival. If it was shifted to the arrival of the cargo based on entry versus based on time of arrival, many of the operational problems would be resolved.

As I mentioned before, there is a mass confusion, and we feel amongst not only the brokerage industry but against the importing industry on the fact of what exact details are actually needed in the transmission and the actual relief required. A good example

would be, part of the transmission—would be the flag of the vessel. A lot of time and resources are devoted to find that one piece of information when in fact it has no bearing on the admissibility of the cargo itself under the Bioterrorism Act.

Just to briefly summarize some of the areas that we feel have some real serious concerns. There is no validation being done on the data that is being transmitted in. We have no feedback from either Agency whether that data is correct or not. We only get confirmation that the data has been transmitted.

There is a mismatch between the data bases that are being used. The registration data base, which is confidential in the Food and Drug Administration, is compared to the data base that is being used in the Customs and Border Protection, which is an 18-year-old data base and very corrupted. Industry has no way of altering that or changing that or amending it.

Also the PNSI, that is the Prior Notice System Interface by Food and Drug, has some very serious concerns. In fact, it was designed for very limited use, not for the mass amount of commercial information being transmitted, and that is the main backup system for the initial ABI system or automated broker interface that we are using now to transmit data via Customs and Border Protection. We have had two major shutdowns. Both shut downs had demonstrated that the system is incapable of handling it properly, timely, in the present form.

Again, as related earlier, the samples coming into the United States do not pose a serious health threat when they are going for laboratory analysis only, and that should be addressed. Again, vast amounts of duplicate information, we transmit not only the prior notice data, but the admissibility data through Food and Drug. That is two separate admissions with a large amount of duplicate information in addition to duplicated indicated information being transmitted to Customs and Border Protection.

We feel some of these fixes need to be done prior to the August 12 implementation date. And we feel that consideration should be given to expand that. The final or not the final but the present comment period will end July 13, which only gives 30 days for the Agencies to make adjustments to the system which we believe is flawed, and we have made comments to that fact. And then, in fact, it is going to take time for industry to make the same type of adjustments within their automated systems. Again, by pushing back the implementation date, we feel that will be a benefit for both the Agencies to do their job better and mostly for industry to adjust properly.

I thank the committee for the time given to me to address some of these concerns, and I will be willing to answer any specific questions they may have. Thank you.

[The prepared statement of Roger Clarke follows:]

PREPARED STATEMENT OF ROGER CLARKE, WILLIAMS AND CLARKE CO.

I. INTRODUCTION

Good morning. My name is Roger Clarke and it is an honor to participate in this hearing today. I am here to represent a broad cross-section of the U.S. importing public. My own company is Williams Clarke Company, a licensed customs brokerage and OTI firm located in Los Angeles, California, that handles a large number of food import accounts. I am the Chair of the FDA Committee of the Pacific Coast Council

of Customs Brokers and Freight Forwarders Associations. The Pacific Coast Council is the voice of the customs brokers, forwarders and NVOCCs in California, Oregon and Washington, the nation's largest international trade gateway.

I am also speaking today on behalf of the National Customs Brokers and Forwarders Association of America, representing customs brokers and forwarders nationwide; the Agriculture Ocean Transportation Coalition, representing agriculture exporters and importers nationwide; the Coalition of New England Companies for Trade; and the New England Seafood Producers Association.

What these groups have in common is this: they all deal in food imports covered by the Prior Notice provisions of the Bioterrorism Act, and they each have concerns regarding how these provisions are being implemented, and how they will impact legitimate food imports once full enforcement begins.

II. BACKGROUND

To begin, allow me to say that the organizations I represent support the intent of the Bioterrorism Act of 2002, which was to protect our nation's food supply from the threat of bioterrorism. As those who import food and process such imports, we are ready to do what is necessary to achieve the objectives of the Act. Further, we recognize that FDA has been given an enormous task in implementing the food provisions of the Act, without significant additional resources. We are pleased that FDA had the foresight to invite CBP to assist in implementing and enforcing the Prior Notice provisions, and to utilize the ABI/ACS system for submission of Prior Notice.

Despite the efforts of both FDA and CBP to develop and implement a workable Prior Notice system, there are significant flaws with the program that must be addressed before the final phase of enforcement begins on August 12. We are concerned that if these issues are not addressed, there is significant potential for legitimate food imports to be stopped at the docks—an expensive exercise for the food importer, and we believe a waste of precious FDA resources needed to prevent bioterrorism.

III. WHAT NEEDS TO BE FIXED

Each of our industry associations has submitted comments to FDA detailing the issues which we believe need to be addressed prior to full enforcement. I will mention only a few of the major issues which impact the ability of the food importing public to comply with the objectives of the Act.

A. The FDA Prior Notice System Interface, PNSI, needs to be ramped up to accommodate all Prior Notice submissions in case of ABI system failure. As the Committee likely knows, the majority of Prior Notice submissions are sent through the Customs ABI/ACS system. When this system is down the PNSI system must be capable of handling all of the overload. Currently PNSI is insufficiently robust to handle the volume processed in ABI/ACS, and has built-in inefficiencies that render it unsuitable for commercial use even when it is not under stress.

B. We have advocated that the Customs ABI/ACS system be reprogrammed to accept 100% of all Prior Notice submissions so as to eliminate the need for filers to operate in both PNSI and ABI/ACS. Thus, we are very pleased that the new "Independent Prior Notice" program will allow filing of Prior Notice through ABI/ACS independent of the Customs entry filing. However, as this program has just recently unveiled, the importing public needs time to make the necessary programming changes in order to avail itself of the program. We encourage FDA to delay full enforcement until the new "Independent Prior Notice" system is fully operational.

C. Safeguards are needed to protect the parties of interest from unauthorized filing of Prior Notice on their behalf. To this end, FDA could require those who submit Prior Notice to have power of attorney to act on behalf of the party of interest, or could license submitters. The current system does not protect against duplicate Prior Notice filings, and could lead to confusion in an emergency situation.

D. The Prior Notice system should be revised to allow greater ability to correct errors after the Prior Notice has been submitted—even if the change occurs after the Prior Notice is due. For example, often product changes hands on the water, or a sale falls through and another importer is identified after the product has arrived in the U.S. This is customary business practice. Under the current rule, it wouldn't be possible to make the change without risking significant penalties, or possibly even rejection of cargo. Again, we have a suggestion that would address this problem as well.

E. Certain exemptions are needed for pre-purchase and trade samples used exclusively for research and development or laboratory analysis, and thus not for sale or distribution to the public; household goods (personal effects and property) shipped to the U.S.; and unadulterated U.S. exports that have been returned to the U.S.

F. The reporting timeframes for Prior Notice and CBP's Advance Notice should be harmonized to mitigate the burden and expense on food importers of meeting both requirements.

G. Congress should amend the Act to eliminate the requirement that Prior Notice be submitted no earlier than 5 days before arrival in the U.S. We cannot fathom the reasoning behind such a requirement. After all, CBP is screening cargo data 24 hours prior to vessel loading at the foreign port.

H. The Prior Notice system absolutely must be revised to assure that the party who submits Prior Notice is notified immediately if the product is refused entry due to Prior Notice violations. Currently only the carrier, who has no ability nor incentive to resolve the refusal, is notified.

I. We urge FDA to eliminate the existing requirement for separate Prior Notice based on packaging and quantity. We do not believe there is any security justification for imposing this costly and unnecessary burden on the importing public.

J. Last, but certainly not least, FDA needs to provide further education and guidance to the food import community prior to full enforcement. FDA did a very effective job of providing training on the basic structure of the Prior Notice system. But food importers have questions related to practical application of the system to their import operations, and are having difficulty getting answers. We believe that it is clear that further clarification is needed. FDA must find a way to reach out to the regulated public to provide the education needed to assure greater compliance. This could be accomplished through additional guidance documents, educational seminars, web-based training, etc. FDA's own Compliance Policy Guide states that such outreach would continue throughout the eight months between implementation and full enforcement. Yet this has not occurred, and we feel it is needed.

Again, these are just some of the revisions to the Prior Notice program that we feel are needed to make it workable for those of us involved in importing food into this country.

IV. OUR RECOMMENDATION TO CONGRESS AND FDA

As previously noted, we support the objective of safeguarding our nation's food supply. We believe that the current Prior Notice system could be modified in such a way that would maintain the safeguards currently in place under the Act, while alleviating some of the burden on the importing public, as well as on FDA and CBP.

Instead of requiring Prior Notice *before arrival of the cargo in the U.S.,* we believe that Prior Notice should be required *prior to release of the cargo by CBP.* This means that product would not be refused entry for lack of Prior Notice, but could never enter the stream of U.S. commerce until FDA had received—and reviewed—the Prior Notice submission. Since CBP already screens cargo manifest data to assure that its physical presence poses no hazard to the U.S., it seems that FDA's focus of assuring that food for consumption in the U.S. is safe for people (and animals) could just as well be achieved by assuring that no shipment is released for consumption until and unless the Prior Notice requirement have been met. Until such time as the cargo is released, it would (and, in fact, currently does) remain in the continuous custody of CBP, thereby posing no threat to the consuming public.

Such a mechanism would address several of the key concerns I have already raised, such as problems where one cannot currently meet the Prior Notice requirements through the ABI/ACS system for live entry items, the need to harmonize FDA and CBP reporting timeframes, and the current inability to make critical revisions to the Prior Notice after cargo has arrived in the U.S. Under the system I have just described, cargo wouldn't be refused entry for an unavoidable error—one would simply re-file and await the requisite release by FDA (and CBP), with no penalty. In effect, the penalty on the importer would be that the cargo would be held until the proper Prior Notice were filed and approved by FDA. The system would also capture cargo entering Foreign Trade Zones, or moving under "T&E"—if such cargo were subsequently destined for domestic consumption one would need to file a "Consumption Entry" with Customs, and such entry would be contingent upon review and approval of Prior Notice by FDA.

We highly encourage the Committee and the agencies to consider this revision to make a more workable—and equally effective—Prior Notice system. In fact, we believe this system would be significantly more effective, since it would assure that FDA and CBP do not waste valuable resources on enforcement actions against legitimate food imports that pose no threat to the public.

V. ENFORCEMENT

I would like to make a few comments on the enforcement of the Prior Notice provisions. First, we have been urging FDA to postpone full enforcement until the final

changes to the Prior Notice system are made, AND the food import community is given both the time and guidance needed to accommodate these changes. I think I can speak for the entire food import community when I say we want to be in compliance, and we don't want our cargo sitting on the docks, or in a General Order warehouse because what we thought was a proper Prior Notice filing turned out to be incorrect or inadequate. Until the program is finalized—presumably sometime after July 13—we cannot be certain what will be expected of us. What we do know is that we will need more than 30 days to understand the most recent changes and make the programming revisions needed to accommodate the changes. Thus we are asking FDA to postpone the final enforcement phase until 60-90 days after FDA finalizes the Prior Notice System.

Second, since there will likely be glitches that appear only after full enforcement, we encourage FDA not to finalize the Interim Final Rule without providing additional opportunity for public comment. We suggest that this final comment period begin 6 months after full enforcement takes effect, and that the public be given a minimum of 60-90 days to make its final comments on the system. This way we can be sure to have a Prior Notice system that works for everyone.

Finally, with regard to the FDA's most recent guidance on penalties, we have serious concerns that we hope the agency will address:

1. Despite the fact that all administration of the Bioterrorism regulations has been centralized within FDA Headquarters, to the purposeful exclusion of the field offices, FDA has announced that penalties will be determined at the Port level. We feel this will lead to inconsistencies and "port shopping," and that penalties are best handled by Headquarters as well.
2. We disagree with FDA's decision to penalize both the submitter and the transmitter for an untimely filing.
3. Since many entries/importations have numerous Prior Notice transmissions, an error on one of the transmissions could generate numerous violations.
4. The first violation, option 1 amount is set at $500.00 for inaccurate PN and treats all inaccuracy the same (clerical error vs. misstatement of fact.

VI. CONCLUSION

I greatly appreciate the opportunity to provide input to the Committee on implementation of Title III of the Bioterrorism Act. I would like to close by emphasizing that we all are striving towards a common goal—that of ensuring the safety of our food supply. We believe this can be achieved without significant disruption to the trade if certain key elements are revised to reflect common business practices. We highly recommend that the Committee and the agencies consider our proposal to condition release of cargo by CBP on receipt and approval of Prior Notice by FDA. We strongly believe this would resolve many of the issues that continue to plague the current Prior Notice system. Finally, I would like to commend both FDA and CBP for their efforts to implement this new program within a very tight timeframe, and with very little additional resources. We recommend that the Committee, in recognition of both the importance and scope of this new security program, provide both agencies with the funding needed to meet the intent of the Bioterrorism Act.

Thank you.

Mr. BILIRAKIS. Thank you very much, Mr. Clarke.

Mr. French.

STATEMENT OF DAVID FRENCH

Mr. FRENCH. Mr. Chairman and Members of the subcommittee, I am David French, Senior Vice President of Government Relations for the International Foodservice Distributors Association, and I thank you for the opportunity to testify today on behalf of IFDA's 130 broadline and specialty food service distributors.

IFDA strongly supports the purposes of the Bioterrorism Act, and our members are committed to safeguarding the quality, safety and integrity of the product that they distribute. IFDA members operate more than 550 facilities and sell more than $75 billion worth of food and related products to restaurants and institutions in the food-away-from-home business. The average IFDA member has approximately $50 million in annual sales and handles slightly

more than 2 million cases of foodservice product per year. Implementation of the food provisions of the 2002 law seems to be going very well.

But before I comment on what the FDA has done well, I want to spend a moment discussing the looming threat of FDA's record-keeping rule, which we view as the most difficult and burdensome of the regulations required by the Bioterrorism Act. The interim final rule on record maintenance and inspection has been delayed for several months. IFDA is hopeful that FDA has been using this time to undertake a substantive rewrite of the proposed rule because our industry has expressed many serious reservations about the initial FDA proposal.

I would like to mention a few of the problems we saw in the proposed rule. The Bioterrorism Act calls for firms to maintain records of their transactions and to make these records available to the FDA to assist in investigations. On its face, these seem to be reasonably simple requirements. After all, foodservice distributors typically retain records for at least 2 years. Food firms also routinely conduct voluntary recalls of misbranded or adulterated food products, so all parts of the food distribution business have experience with conducting trace-back and trace-forward investigations. In fact, it is common for our companies to practice mock recalls at the request of their larger customers.

Unfortunately, rather than building on the existing systems that food companies employ to keep track of product and conduct recalls, the FDA proposed a rigid bureaucratic and one-size-fits-all rule. If key elements of the proposal find their way into the final rule, many of the companies in our industry will be facing multi-million dollar information system upgrades that will yield no significant improvement in the effectiveness of food investigations and recalls. I would add that compliance is a very serious matter insofar as failure to maintain the required records or failure to provide access to these records within the required timeframe subjects the company to civil and criminal liability.

One element of the proposed rule that concerns us is the requirement that companies retain the lot number or other identifier for each article of food that they send or receive. The requirement to record lot numbers is problematic for foodservice distributors. Distributors handle food in pallets and cases. A single pallet may contain food from multiple lots. And the lot numbers often appear only on the individual food packages. There is no government or industry standard for location or presentation of lot numbers so they may appear on product packages or on cases, may be embedded in the UPC code or stand alone and may take a variety of forms. Most importantly, lot numbers are not generally included on invoices. In many cases, the requirement to record lot numbers would mean the distributors must break open cases and search for lot numbers to record. This is a key point and an issue that has people in charge of logistics and operations very worried.

Therefore, we have requested the FDA give companies discretion to determine what is an appropriate identifier. Most distributors track food by purchase order number. All foods have a purchase order and a purchase order number. If a manufacturer recalls a

product, it is an easy matter to determine a purchase order number, trace the product and remove it from commerce.

Another significant concern involves the timeframe for production of records. The proposed rule sets very short timeframes within which companies are required to make records available to FDA. As little as 4 hours is permitted if the request is made during normal business hours. Moreover, it is not entirely clear from the proposed rule when the clock will begin to run.

Section 306 of the Bioterrorism Act makes failure to produce records within this timeframe a prohibited act. Under the Federal Food Drug and Cosmetic Act, a prohibited act is criminal offense and company executives can be held personally criminally liable. Given the serious consequences of noncompliance, we view the imposition of a hard and fast 4-hour timeframe as unreasonable. While these records can be retrieved quickly in an emergency, a 4-hour deadline during normal business hours will not always be feasible. And we question whether imposition of criminal liability for a violation such as this is appropriate.

We are also concerned that the FDA pay heed to the legislative history regarding when it may obtain access to records. Because the Bioterrorism Act gives FDA access to highly sensitive commercial information, it is important that the new records access authority be used appropriately. While the Bioterrorism Act requires the FDA to take appropriate measures to prevent unauthorized disclosure of trade secrets or confidential information, the proposed rule did not address this issue.

The FDA is now three-fourths of the way through the rulemaking process. The interim final rules on registration and prior notice and the final rule on administrative detention have all been written. And the foodservice distribution industry is generally pleased with the significant cooperation and understanding that the FDA has shown in responding to the industry's concerns. FDA has done an impressive job of listening and responding to various workability issues raised by numerous comments on the rulemaking process, and the Agency should be commended for this.

In the brief experience that our companies have had with these rules, they have reported very few supply disruptions or concerns. Smooth implementation of the first three regulations is due to several factors which have been summarized in my written submission.

While we are generally pleased with the implementation of the first three rules under the Bioterrorism Act, there are some serious concerns with regard to the prior notice rule, FDA's phasing in enforcement of the rule through Agency discretion and educational outreach. As mentioned earlier, no real education seems to be happening. While FDA is keeping track of and posting data on a number of inadequate prior notices, FDA is not telling industry why these prior notices are deficient. We hope that FDA will step up its educational efforts before full enforcement of the prior notice rule begins on August 13.

In addition, our members are reporting significant problems with FDA failing to make timely inspection decisions along the Canadian border. Whether the problems are related to the Bioterrorism Act or prior notice or simply a reflection of a sizable number of new

inexperienced inspection personnel on the job, we have heard that many products imported from Canada are not receiving timely decisions from FDA. In some cases, FDA inspectors are taking an inordinate amount of time to decide whether or not to sample imported product. As the legislative history of the act makes clear, FDA review of prior notice should not delay or unnecessarily disrupt the flow of commerce.

Mr. BILIRAKIS. Please summarize.

Mr. FRENCH. I am close to concluding, Mr. Chairman.

We understand that implementation involves a learning curve for FDA as well as industry, and we hope that these delays will disappear.

Thank you for the opportunity to present this statement, and I am happy to answer any questions.

[The prepared statement of David French follows:]

PREPARED STATEMENT OF DAVID FRENCH, INTERNATIONAL FOODSERVICE DISTRIBUTORS ASSOCIATION

Mr. Chairman, Mr. Waxman, and members of the Committee, I am David French, senior vice president of government relations for the International Foodservice Distributors Association, and I thank you for the opportunity to testify today regarding the Food and Drug Administration's implementation of the food provisions of the Bioterrorism Act of 2002. IFDA strongly supports the purposes of the Bioterrorism Act, and our members are committed to safeguarding the quality, safety, and integrity of the products that they distribute.

IFDA is a trade organization representing foodservice distributors throughout the U.S., Canada, and internationally. IFDA's 130 members include broadline and specialty foodservice distributors that supply food and related products to restaurants and institutions in the "food away from home" business. IFDA members operate more than 550 facilities, and sell more than $75 billion in food and related products. The average IFDA member has approximately $50 million in annual sales and handles slightly more than two million cases of foodservice product per year. Formerly a division of Food Distributors International, IFDA was established as an independent trade association on January 1, 2003.

In general, I can report that the implementation of the food provisions of the 2002 law has gone much more smoothly than expected. But before I comment on what the FDA has done well, I want to spend a moment discussing the looming threat of the FDA's recordkeeping rule. The recordkeeping rule is generally viewed as the most difficult and burdensome of the regulations required by the Bioterrorism Act.

As you know, the interim final rule on record maintenance and record inspection has been delayed for several months. IFDA is hopeful that the FDA has been using this time to undertake a substantive rewrite of the proposed rule, because our industry has expressed many serious reservations about the initial FDA proposal. I'd like to briefly mention a few of the problems we saw in the proposed rule.

The Bioterrorism Act calls for food firms to maintain records of their transactions for some length of time and to make these records available to FDA to assist in trace back and trace forward investigations. On its face, these seem to be reasonably simple requirements. After all, foodservice distributors typically retain records for at least two years. Food firms also routinely conduct voluntary recalls of misbranded or adulterated food products, so all parts of the food distribution business have experience with conducting trace back and trace forward investigations.

Unfortunately, rather than building on the existing systems that food companies employ to keep track of product and to conduct recalls, the FDA proposed a rigidly bureaucratic and one-size-fits-all rule. If key elements of the proposal find their way into the final rule, many of the companies in our industry will be facing multi-million dollar information system upgrades that will yield no significant improvement in the effectiveness of food investigations and recalls. I would add that compliance is a very serious matter insofar as failure to maintain the required records, or failure to provide access to these records within the required time frame, subjects a company to civil and criminal liability.

One element of the proposed rule that concerns us is the requirement that companies retain the lot number "or other identifier" for each article of food that they send or receive. A requirement to record lot numbers is problematic for foodservice dis-

tributors. Distributors handle food in pallets and cases. A single pallet may contain food from multiple lots, and the lot numbers often appear only on the individual food packages. There is no government or industry standard for location or presentation of lot numbers, so they may appear on product packages or on cases, may be embedded in the UPC code or stand alone, and may take a variety of forms. In many cases, a requirement to record lot numbers would mean that distributors must break open pallets and cases and search for the lot numbers to record. This is a key point, and an issue that has the people in charge of logistics and operations in IFDA member companies very worried.

Therefore, we have requested that FDA give companies considerable discretion to determine what is an appropriate identifier. Most distributors track food by purchase order number. All foods have a purchase order and purchase order number. If a manufacturer recalls a product or if it is necessary to trace a food shipment for any other reason, it is an easy matter to determine a purchase order number, trace the product, and remove it from commerce.

Another significant concern that the foodservice industry has raised regarding the proposed rule involves the time frames for production of required records. The proposed rule sets very short time frames within which companies are required to make records available to FDA in response to an official request—only four hours if the request is made during normal business hours. Moreover, it is not entirely clear from the proposed rule when the clock begins to run. Section 306 of the Bioterrorism Act makes failure to produce records within this time frame a "prohibited act." Under the Federal Food, Drug, and Cosmetic Act, a "prohibited act" is a criminal offense, and company executives can be held personally criminally liable.

Given the serious consequences of non-compliance, we view the imposition of a hard-and-fast four-hour time frame as unreasonable. While these records can be retrieved quickly in an emergency, a 4-hour deadline during normal business hours (or an 8-hour deadline outside of normal business hours), as proposed by FDA, is not feasible. IFDA agrees that FDA must have quick access to records in the event of an emergency. Imposition of criminal liability for violation of such a short timeframe, however, is inappropriate. Instead, FDA should require that records be made available in a reasonable period of time. As the courts have been able to determine what constitutes reasonable times and places for FDA inspection under FD&C Act section 704, so too can the courts apply a reasonableness standard to the time frames for records access.

A third concern we have deals with the circumstances of records access. We are concerned that FDA pay heed to the legislative history regarding when it may obtain access to records. According to one of the sponsors of the Bioterrorism Act, John Shimkus (R-IL), FDA "shall ensure that adequate procedures are in place to ensure agency personnel will not have access to records without a specific reason and need for such access, and that possession of all copies of records will be strictly controlled . . ." *Cong. Rec.* E2388 (Dec. 20, 2001). Because the Bioterrorism Act gives FDA access to highly sensitive commercial information, it is important that the new records access authority be used appropriately and not abused and that strong protection be put in place to prevent inappropriate release of sensitive information. While the Bioterrorism Act requires that FDA take appropriate measures to prevent unauthorized disclosure of trade secret or confidential information, the proposed rule did not address this issue.

The FDA is three-fourths of the way through the rulemaking process. The interim final rules on registration and prior notice and the final rule on administrative detention have all been written, and the foodservice distribution industry is generally pleased with the significant cooperation and understanding that the FDA has shown in responding to the industry's concerns. FDA has done an impressive job of listening and responding to various workability issues raised by numerous comments during the rulemaking process, and the agency should be commended for this.

In the brief experience that our companies have had with these rules, they have reported very few supply disruptions or concerns. Smooth implementation of the first three regulations is due to several factors. First, in the case of the prior notice rule in particular, FDA made a serious effort to address industry concerns raised during the rulemaking and the interim final rule was far less onerous than the proposed rule. Second, FDA has been phasing in enforcement of the prior notice and registration rules, so implementation problems may become more noticeable in the near future when full enforcement begins. Third, the prior notice rule has little direct impact on foodservice distributors, since with a few exceptions, foodservice firms do not import product directly. Instead, they work with importers and brokers who handle transactions with foreign suppliers. Importers may also be keeping their inventories larger than usual in order to minimize disruptions. Finally, firms in our

industry, following FDA guidance, generally work with known suppliers. These suppliers are likely to be larger and more capable of working within the FDA rules.

While we are generally pleased with implementation of the first three rules under the Bioterrorism Act, there are some serious concerns. With regard to the prior notice rule, as previously mentioned, FDA is phasing in enforcement of the rule. We are currently in a period of enforcement discretion and educational outreach. Unfortunately, no real education is happening. While FDA is keeping track of and posing data on the number of inadequate prior notices it receives, FDA is not telling industry why these prior notices are deficient. We hope that FDA will step up its educational efforts before full enforcement of the prior notice rule begins on August 13.

In addition, our members are reporting significant problems with FDA failing to make timely inspection decisions along the Canadian border. It is not clear whether this problem is related to the Bioterrorism Act and prior notice or simply a reflection of a sizable number of new, inexperienced inspectional personnel on the job; but we have heard that many products imported from Canada are not receiving timely decisions from FDA. In some cases, FDA investigators are taking an inordinate amount of time to decide whether or not to sample imported product. As the legislative history of the Bioterrorism Act makes clear, FDA review of prior notice "should not delay or unnecessarily disrupt the flow of commerce." *Cong. Rec.* E2389 (Dec. 20, 2001). We understand that implementation involves a learning curve for FDA as well as industry, and we hope that these delays will disappear.

Thank you for the opportunity to present this statement, and I am happy to take any questions.

Mr. BILIRAKIS. Thank you very much for your statement.

Ms. Stout.

STATEMENT OF SUSAN M. STOUT

Ms. STOUT. Good morning Mr. Chairman.

I am Susan Stout. I am Vice President of Federal Affairs of the Grocery Manufacturers of America. We are led by a Board of 42 chief executive officers, and GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than $500 billion, GMA members employ more than 2.5 million workers in all 50 States.

The subcommittee hearing today is timely and a useful review of where things stand 2 years following enactment of the Bioterrorism Act. Thus far, FDA, as you know, has issued final regulations on detention, interim final rules on registration and prior notice and a proposed rule on recordkeeping. The FDA has been accessible and open to suggestions to improve the workability of these regulations from those who have to make the regulations work, the food industry.

No regulation is ever perfect, and I am not suggesting that the FDA's bioterrorism regulations are perfect. The food industry has been concerned about the provision for prior notice of imported foods from the beginning of this process. When FDA issued proposed regulations to implement prior notice in February 2003, our worst fears were realized. That proposal would have been costly, duplicative, unworkable and likely to have led to lines at the U.S. entry points that would have rivaled those at airport security checkpoints.

GMA's comments on the proposed prior notice regulations discussed all of the problems with the FDA proposal and made suggestions for improvements. To its credit, the interim final regulation that FDA issued on October 10, 2003 did address most of the egregious workability problems, but we don't know whether the prior notice system will work.

Let me explain what I mean by that. FDA has properly provided for a period of time after publication of the interim final rule for itself, Customs and Border Protection and the food industry to become educated about the requirements and to implement systems to enable compliance. This educational phase is scheduled to conclude in the middle of August, at which time full enforcement begins. We do not believe that anyone can confidently predict what will happen when full enforcement does begin.

However, although companies have been submitting prior notices since last December, FDA has provided little if any feedback on deficiencies of specific notices. Companies can only guess what problems might have occurred. Additionally, FDA's own data show that more than one-third of prior notices submitted as recently as this April were deemed incomplete. If FDA were now fully enforcing the requirement, more than 50,000 notices per week would be ineffective and the food covered by those notices denied entry into the United States.

Another troubling issue with prior notice relates to the FDA imposed requirement that all prior notices contain the facility registration number where the food was produced. In some instances, it is not possible to satisfy this requirement, yet FDA has not provided a solution. This requirement is particularly problematic for trade and product samples.

Congress intended prior notice to assist the FDA in allocating resources to examine and inspect potentially high-risk shipments of food. FDA's limited resources should not be spent examining food product samples that are not for public consumption or retail sale and clearly do not present major food security issues. Easing this burden for product samples would have to ensure that food companies, in order to conduct their testing, do not have to relocate the product analysis facilities outside of the United States. FDA must provide some relief.

The second rulemaking of particular concern is recordkeeping. Under the Bioterrorism Act, FDA is authorized to require the maintenance of records of food to show the immediate person from whom the food was received and the immediate person to whom the food was distributed. These records are intended to assist FDA in tracing the movement of food in the event of a serious problem involving that food.

FDA has proposed to require food companies to maintain records that include lot or production codes for product delivered to the retail stores. GMA has vigorously objected to this proposed requirement as contributing nothing to food security while being incredibly time-consuming and burdensome. We have urged FDA to remove this requirement from the recordkeeping regulation. I have inserted a copy of our comments on this subject in my testimony.

The delivery of food to retail stores occurs in various ways. A growing number of our food companies use so-called direct-store delivery. In direct-store delivery, the food manufacturer delivers product to the retailer, restocks the shelf, replacing older product with new, using company vehicles and company employees. I am sure you have seen the GMA company trucks at your local grocery stores. If there is a problem with the particular food, the manufacturer will move all of the potentially offending food, not just a spe-

cific lot or code amount from distribution until the magnitude and scope of the problem is determined. Retailers will do exactly the same thing.

We very much hope that in the final recordkeeping regulation, FDA will remove this ill advised and unnecessary proposed requirement for lot and production codes.

Thank you, Mr. Chairman.

[The prepared statement of Susan M. Stout follows:]

PREPARED STATEMENT OF SUSAN M. STOUT, VICE PRESIDENT, FEDERAL AFFAIRS, GROCERY MANUFACTURERS OF AMERICA

Mr. Chairman and Members of the Subcommittee, I am grateful for the opportunity to participate this morning in this important hearing.

GMA is the world's largest association of food, beverage and consumer product companies. Led by a board of 42 Chief Executive Officers, GMA applies legal, scientific, and political expertise from its more than 140 member companies to vital public policy issues affecting its membership. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry. With U.S. sales of more than $500 billion, GMA members employ more than 2.5 million workers in all 50 states.

A little over two years ago, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act. GMA worked closely with the Members and staff of this Subcommittee and the full Energy & Commerce Committee to ensure that the additional authorities provided to Federal regulators were well considered and likely to contribute to increased food security, and not merely increased burdens on the food industry. The Subcommittee's hearing today is a timely and useful review of where things stand two years after enactment.

Before turning to the Bioterrorism Act I want to briefly mention an important GMA program—Project Vigilance. Ensuring the security of the food supply is the responsibility of the food industry as well as the government. Project Vigilance encompasses our actions immediately following September 11th to help assure the security of food, beverages and consumer products. Included with my testimony is a description of the program.

The Bioterrorism Act requires FDA to undertake numerous rulemakings. Specifically, FDA was required to develop regulations on food facility registration, administrative detention, prior notice of imported foods, and recordkeeping. I intend to spend the bulk of my testimony discussing issues related to prior notice and recordkeeping. Before turning to those two subjects, however, I want to share with the Subcommittee a general observation about the development of these regulations by FDA to implement the Bioterrorism Act.

Thus far, FDA has issued final regulations on detention and interim final rules on registration and prior notice. The final regulation on recordkeeping is expected soon. Throughout all of these rulemaking proceedings, the FDA staff has been accessible, open to suggestions to improve the regulations, and willing to address issues in the regulations to improve workability. No regulation is ever perfect and I am not suggesting that FDA's bioterrorism regulations are perfect. But, FDA is certainly to be commended for the process that it has used to develop these regulations and for its willingness to modify proposed regulations based on comments from those who have to make the regulations work—the food industry.

Throughout the development of the Bioterrorism Act, the food industry was most concerned about the provision for prior notice of imported foods. Our concerns were based on unease about the burden on importers, questions about integration of the FDA requirements with those of the U.S. Customs and Border Protection, and, ultimately, the effects on the cost and availability of food if the prior notice requirements impeded the importation of food. When FDA issued proposed regulations to implement the prior notice requirement in February of 2003, our worst fears were realized. That proposal would have been costly, duplicative, unworkable, and quite likely to have led to lines at the various entry points through which food enters the United States that rivaled those at airport security check points.

GMA's comments on the proposed prior notice regulations discussed all of the problems with the FDA proposal and made suggestions to improve the prior notice system. To its credit, the interim final regulation that FDA issued on October 10, 2003, addressed most of the most egregious problems with the proposal—the time frames for submission of the notice were shortened, coordination with Customs was

enhanced, and numerous other "workability" issues were solved. But, we don't yet know whether the prior notice system will work. Let me explain.

FDA has properly provided for a period of time after publication of the interim final rule for itself, Customs and Border Protection and the food industry (including food manufacturers, importers, and persons involved in the transportation and distribution of food) to become educated about the requirements and to implement systems to enable them to comply. Currently, this "educational" phase is scheduled to conclude in the middle of August; FDA and CBP will then commence full enforcement.

We do not believe that anyone can confidently predict what will happen when full enforcement begins. First, although companies have been submitting prior notices since last December, FDA has provided little if any feedback on deficiencies in specific notices. Companies can only guess what problems might have occurred. Second, FDA's own data show that more than one-third of prior notices submitted as recently as April were deemed "incomplete." ("Compliance Summary Information: Prior Notice," April 1, 2004; updated May 2004. U.S. Food and Drug Administration). If FDA were now fully enforcing the requirement, more than 50,000 notices per week would be ineffective and the food covered by those notices denied entry into the United States.

One of the most troubling issues with prior notice relates to the FDA-imposed requirement that all prior notices contain the facility registration number of the facility where the food was produced. In some instances, it is not possible to satisfy this requirement, yet FDA has not provided a solution. The requirement to provide the registration number in a prior notice is a particular problem for trade and product samples. U.S. food companies routinely import samples for analysis and review. Some of these samples are products distributed by the company overseas, while others are samples of competitor's products or samples of food or food ingredients made by foreign companies who would like to do business with the U.S. company. When the samples are intra-company, the registration number can be obtained, but the burden to submit a prior notice, individually, for every one of these products is excessive. Further, when the sample is a competitor's product, access to the registration number is ordinarily not possible. In addition, if the sample is from a company not doing business in the United States, the company is not required to register its facilities and thus does not have a facility registration number.

FDA must provide some relief for the importation of samples. The routine importation of small quantities of food product samples simply does not present major food security issues. Prior notice is intended to assist FDA in allocating resources to examine and inspect potentially high risk shipments of food. We do not believe that FDA should devote its limited resources to the routine examination of food product samples. Easing the prior notice burden for product samples would help to ensure that food companies do not have to relocate product analysis facilities outside the United States (to avoid the expense and hassle of filing notices for every sample or dealing with the problem of filing notices where registration numbers are not available). FDA should develop a category for which a registration number is not required such as sample products that will not be consumed by the general public or that are not intended for retail sale.

The second rulemaking of particular concern is recordkeeping. Under the Bioterrorism Act, FDA is authorized to require the maintenance of records of food to show the immediate person from whom the food was received and the immediate person to whom the food was distributed. These records are intended to assist FDA in tracing the movement of food in the event of a serious problem involving that food. FDA issued proposed recordkeeping regulations on May 9, 2003. Final regulations are expected to be published soon.

In the recordkeeping proposal, FDA proposed to require that food companies maintain records that included lot or production codes for product delivered to retail stores. GMA has vigorously objected to this proposed requirement as contributing nothing to food security while being incredibility time consuming and burdensome. We have urged FDA to remove this requirement from the recordkeeping regulation. A copy of GMA's comments is included with my testimony.

The delivery of food to retail stores occurs in various ways. A growing number of food companies use so-called direct store delivery. In direct store delivery, the food manufacturer delivers product to the retailer using company vehicles and employees. You have all seen GMA's member company trucks at your local grocery store—these are direct store companies. The delivery employees not only deliver the food to the store, but restock the shelves—removing older product and replacing it with new. It would be virtually impossible for these employees to capture the lot or production code on each bottle or can of beverage or each container of snack foods as they stock the shelf.

Importantly, this information is of little value to FDA. If there is a problem with a particular food, the manufacturer will remove all of the potentially offending food from distribution until the magnitude and scope of the problem is determined. Retailers will do the same. Thus, knowing that a particular product of concern with a particular lot number was delivered to a specific retailer is not only extremely difficult to obtain, but of little value.

We very much hope that in the final recordkeeping regulation FDA will remove the ill-advised proposed requirement for lot and production codes.

Mr. Chairman and Members of the Subcommittee, we welcome your oversight. With the consolidation of the USDA Animal Plant and Inspection Services and Customs from Treasury into the Department of Homeland Security, our companies have been experiencing delays, inconsistent enforcement of rules and confusion at the ports of entry. With the implementation of the bioterrorism regulations, we are concerned that these problems will increase. Additional resources may be needed at the borders and we encourage your continued oversight.

I would be pleased to respond to any questions you may have. Again, GMA thanks the Subcommittee for convening these hearings.

Mr. BILIRAKIS. Thank you very much, Ms. Stout.

Mr. Saunders, please proceed.

STATEMENT OF R. DOUGLAS SAUNDERS

Mr. SAUNDERS. Thank you, Mr. Chairman.

Although I am an employee of the Virginia Department of Agriculture and Consumer Services, I am here today as a representative of the Board of Directors of the Association of Food and Drug Officials.

For 108 years, AFDO has served as a major voice for food safety officials in the United States and Canada. AFDO proudly represents State and local government food safety officials at public meetings or briefings where consensus opinions or official comments are presented on a host of food safety and security issues.

Today more than ever, there is a call for unity among health officials in government and all levels and the need to coordinate all available food safety and security resources, particularly those at the integral nodes of our detection system. From that perspective, we would like to offer the following comments relative to the Bioterrorism Act.

AFDO fully supports the FDA as they implement regulations under the Bioterrorism Act. Prior notification of incoming shipments of imported foods and registration of food establishments are absolutely imperative if we are to have any ability at all to effectively control the movement or distribution of foods that are suspected of being compromised through acts of terrorism. We believe that such requirements provide the basis for having greater control of suspect foods and will enhance the capability to more quickly detect nonintentional or intentional adulteration and facilitate immediate removal of suspect food from the channels of commerce.

Early detection and rapid response are essential elements to defend the integrity of our food supply. Prior notification and establishment of registration can only improve those elements. However, we also believe that these components of the Bioterrorism Act must be augmented by additional measures. With imported foods, FDA must do more. The concept of evaluating the safety of imported foods solely at one of the 400 border points is inadequate in our view. FDA needs to move back the borders to the manufacturing site and perform inspections of those food establishments to signifi-

cantly enhance our ability to detect, detain and ultimately remove from commerce intentionally adulterated foods.

Currently, such inspections only take place with respect to low-acid canned foods. This authority must be expanded to cover all food manufacturers located outside of our borders that ship the food products into the United States. In addition, FDA must work closer with State and local government agencies relative to imported foods that are distributed domestically.

Some may suggest that imported foods are a regulatory concern for Federal Agencies alone. These individuals would be wrong. Once imported food gets through the scrutiny of our Federal partners, they become primarily the concern of State and local regulatory agencies. Many States report recalls of imported foods, and the food seizures and embargoes are commonplace for issues that include undeclared allergens, unapproved color additives, undeclared preservatives and pathogens. FDA must develop a means for obtaining this information and utilizing it where appropriate to institute import alerts.

FDA must also consider how to best use State and local laboratory resources as well. The recordkeeping requirements provided by the Bioterrorism Act certainly improves the likelihood that effective trace-backs, trace-forwards or recalls will be facilitated in the event of a terrorist attack against our food supply. Improved trace-back, trace-forward or recall capabilities will significantly enhance the expeditious tracking and removal activities of the FDA when adulteration is detected. It must be noted, however, that, historically, trace-back or trace-forward activities are usually performed by State food safety agencies. It is safe to assume that with the limited resources that are available to the FDA, most trace-back and trace-forward activities will continue to be performed by the States in cooperation with FDA.

Administrative detention is a tool that FDA has needed for many years and a tool that will provide immediate results when it becomes necessary to prevent further distribution of suspect food products. Prior to the granting of this authority by Congress, FDA had to request States to detain, seize or embargo food products when suspect food products were encountered. Through cooperative agreements, FDA has utilized the State's detention authority for many years.

Because the Bioterrorism Act contains the specific requirements when FDA can utilize administrative detention, it will still be necessary for FDA to maintain these cooperative agreements with the States to ensure that suspect foods that do not meet the Federal definition but are still of considerable concern relative to adulteration continue to be legally restrained. Consequently, through the FDA's new detention authority and through continuing cooperative agreements between FDA and the States, the nationwide network of detention capabilities will be substantially strengthened.

For as long as FDA has existed, the cooperative relationship between the FDA and State and local food safety agencies have worked very effectively in protecting our Nation's food supply. These coordinated activities have led to a maximized utilization of Federal, State and local food safety and security resources while eliminating the duplication of food protection activities.

Through these cooperative efforts, State and local food safety agencies have been able to supplement the food safety and security activities of the FDA. In 2002, AFDO conducted a survey of State activities that showed that, during 2001, State programs performed more than 2.5 million inspections of food establishments, more than 3,000 food-borne illness investigations and investigation of over 46,000 consumer complaints, response to over 2,800 emergencies, more than 128,000 enforcement actions, and collection and analysis of over 328,000 food samples.

Based on these figures, more than 80 percent of the food safety and security activities in the United States are performed at the State or local levels. Consequently, it is clear that State and local food safety programs provide the major portion of the shields that must be in place to detect any sort of terrorist act. With the increasing threat of terrorist activities against the food supply, it is paramount that this cooperative and highly integrated State, local and Federal food safety and security system be maintained and strengthened for the deterrence, prevention and detection of terrorist activities.

With that focus, AFDO would like to call attention to a piece of Federal legislation that threatens——

Mr. BILIRAKIS. Summarize it though, please.

Mr. SAUNDERS. H.R. 2699, the National Uniformity For Food Act of 2003, as presently cast undermines our Nation's whole bio-surveillance system by preempting and invalidating many of the State and local food safety laws and regulations that provide the necessary authority for State and local agencies to operate food safety and security programs.

We feel that you need to be aware of our concerns with respect to that legislation and that the cost to the FDA to replace the infrastructure and food safety and security activities currently accomplished at State and local levels is estimated to exceed $500 million.

In conclusion, the Bioterrorism Preparedness and Response Act of 2002 is an immeasurably important and necessary law that further solidifies our Nation's food safety and security system by providing FDA with much needed and long overdue authorities. However, the new FDA authorities can only remain effective if these cooperative relationships between the FDA and State and local food and safety security programs can be maintained and improved. Consequently, for the effectiveness of the Bioterrorism Act to be fully realized, it is absolutely imperative that our current food safety and security programs at all levels remain fully functional and active.

Once again, thank you very much for the opportunity to provide these comments.

[The prepared statement of R. Douglas Saunders follows:]

PREPARED STATEMENT OF R. DOUGLAS SAUNDERS, CHAIR, FOOD SECURITY TASK FORCE, AND BETSY WOODWARD, SPECIAL ADVISOR TO THE BOARD OF DIRECTORS, ASSOCIATION OF FOOD AND DRUG OFFICIALS

Mr. Chairman, and members of the Committee, I am here today as a representative of the Board of Directors and a past president of the Association of Food and Drug Officials (AFDO), to provide testimony on the importance of the Bioterrorism Preparedness and Response Act of 2002 (hereinafter referred to as the Bioterrorism

Act). I would like to thank you for this opportunity to share the perspective of AFDO on an issue that is so vital to the protection of the food and agriculture critical infrastructure of our nation.

For 108 years, AFDO has served as a major voice for food safety officials in the United States and Canada. AFDO proudly represents state and local government food safety officials at public meetings or briefings where consensus opinions or official comments are presented on a host of food safety and security issues. Today, more than ever, there is a call for unity among health officials in government at all levels and the need to coordinate all available food safety and security resources, particularly those at the sentinel nodes of our detection system. From that perspective, we would like to offer the following comments relative to the Bioterrorism Act.

With respect to the four major issues addressed by the Bioterrorism Act, AFDO fully supports the U.S. Food and Drug Administration (FDA) as they implement regulations to address those provisions. Specifically, those provisions include:

- Prior notification of imported foods coming into the United States;
- Registration of food establishments;
- Record keeping to ensure effectiveness of tracebacks, traceforwards and recall activities; and
- Administrative detention of food products.

Prior notification of incoming shipments of imported foods and registration of food establishments are absolutely imperative if we are to have any ability at all to effectively control the movement or distribution of foods that are suspected of being compromised through acts of terrorism. We believe that such requirements provide the basis for having greater control of suspect foods and will enhance the capability to more quickly detect non-intentional or intentional adulteration and facilitate immediate removal of suspect foods from the channels of commerce. Early detection and rapid response are essential elements to defend the integrity of our food supply. Prior notification and establishment registration can only improve those elements. However, we also believe that these components of the bioterrorism act must be augmented by additional measures. With imported foods, FDA must do more. The concept of evaluating the safety of imported foods solely at one of the 400 border points is inadequate, in our view. FDA needs to move back the borders to the manufacturing site and perform inspections of these food establishments to significantly enhance our ability to detect, detain, and ultimately remove from commerce intentionally adulterated foods. Currently, such inspections only take place with respect to low-acid canned foods. This authority must be expanded to cover all food manufacturers located outside of our borders that ship food products into the United States.

In addition, FDA must work closer with State and Local government agencies relative to imported foods that are distributed domestically. Some may suggest that imported foods are a regulatory concern for federal agencies alone. These individuals would be wrong. Once imported foods get through the scrutiny of our federal partners, they become primarily the concern of State and Local regulatory agencies. Many states report recalls, and food seizures or embargoes are commonplace for issues that include undeclared allergens, unapproved color additives, undeclared preservatives, and pathogens. FDA must develop a means for obtaining this information and utilizing it, where appropriate, to institute import alerts. FDA must also consider how to best use State and Local laboratory resources, as well.

The recordkeeping requirements provided by the Bioterrorism Act certainly improve the likelihood that effective tracebacks, traceforwards, or recalls will be facilitated in the event of a terrorist act against our food supply. Improved traceback, traceforward, or recall capabilities will significantly enhance the expeditious tracking and removal activities of the FDA when adulteration is detected. It must be noted, however, that historically, traceback or traceforward activities are usually performed by State food safety agencies. It is safe to assume that with the limited resources that are available to the FDA, most traceback and traceforward activities will continue to be performed by the States, in cooperation with the FDA.

Administrative detention is a tool that FDA has needed for many years, and a tool that will provide immediate results when it becomes necessary to prevent further distribution of suspect food products. Prior to granting of this authority by Congress, FDA had to request States to detain, seize or embargo food products when suspect food products were encountered. Through cooperative agreements, FDA has utilized the States' detention authority for many years. Because the Bioterrorism Act contains specific requirements that define when FDA can utilize administrative detention, it will still be necessary for FDA to maintain these cooperative agreements with the States to ensure that suspect foods that do not meet the Federal definition but are still of considerable concern relative to adulteration, continue to be legally restrained. Consequently, through the FDA's new detention authority,

and through continuing cooperative agreements between FDA and the States, the nationwide network of detention capabilities will be substantially strengthened.

For as long as FDA has existed, the cooperative relationships between the FDA and State and Local food safety agencies have worked very effectively in protecting our nation's food supply. These coordinated activities have led to a maximized utilization of Federal, State and Local food safety and security resources, while eliminating the duplication of food protection activities. Through these cooperative efforts, State and Local food safety agencies have been able to supplement the food safety and security activities of the FDA. In 2002, AFDO conducted a survey of state activities which showed that during 2001, state programs performed:

- More than 2.5 million inspections of food establishments;
- More than 3,000 foodborne illness investigations;
- Investigation of over 46,000 consumer complaints;
- Response to over 2,800 emergencies or disasters involving food products;
- More than 128,000 enforcement actions, including, but not limited to, embargos, seizures and stop sales; injunctions; criminal prosecutions; warning letters; informal hearings; and food recalls; and,
- Collection and analyses of over 328,000 food samples, including more than 252,000 microbiological samples.

Based on these figures, more than 80% of the food safety and security activities in the United States are performed at the State or Local levels. Consequently, it is clear that State and Local food safety programs provide the major portion of the shields that must be in place to detect any sort of terrorist act. With the increasing threat of terrorist activities against our food supply, it is paramount that this cooperative and highly integrated Federal, State and Local food safety and security system be maintained and strengthened for the deterrence, prevention and detection of terrorist activities. With that focus in mind, AFDO would like to call attention to a piece of Federal legislation that threatens to eviscerate this system. The ramifications of this bill, intended or not, will dissolve our nation's biodefense capabilities.

H.R. 2699, the National Uniformity for Food Act of 2003, as presently cast, undermines our nation's whole biosurveillance system by preempting and invalidating many of the State and Local food safety laws and regulations that provide the necessary authority for State and Local agencies to operate food safety and security programs. The pre-9/11 concept embodied in this bill is very much out of line with current threats that confront our food safety and security system. Preempting and invalidating State and Local food safety and security activities will lead to serious ramifications that will be difficult, if not impossible, for our nation to recover from. Specifically, FDA's ability to detect, much less respond, to acts of terrorism will be severely hampered. The cost to the FDA to replace the infrastructure and food safety and security activities currently accomplished at the State and Local levels is estimated to exceed $500,000,000. Our current food safety and security system will be significantly disrupted for many years to come, and our inability to track suspected acts of intentional adulteration will be exploited by those who seek to do harm to our nation. Passage of H.R. 2699, in its current form, which would invalidate State and Local food safety laws and regulations, will effectively eliminate our nation's food biosecurity shields, and will undermine our whole, food safety and biosurveillance capability.

In conclusion, the Bioterrorism Preparedness and Response Act of 2002 is an immeasurably important and necessary law that further solidifies our nation's food safety and security system by providing FDA with much needed, and long overdue authorities, and it ensures the continuing, cooperative efforts of State and Local agencies. However, these new FDA authorities can only remain effective if these cooperative relationships between the FDA and State and Local food safety and security programs can be maintained and improved. Consequently, for the effectiveness of the Bioterrorism Act to be fully realized, it is absolutely imperative that our current food safety and security programs at all levels remain fully functional and active, and that we continue to seek ways in which we can strengthen this highly integrated and cooperative system.

Once again, thank you for this opportunity to provide our comments.

Mr. BILIRAKIS. Thank you Mr. Saunders.

First, I would say, in 5-plus minutes, I know it is very difficult or impossible to present your point of views adequately. And so, you know, I truly invite you to complement your oral remarks and your written statement with any additional comments to us.

We all want the same thing, I like to think, and that is concern for the health and safety of our fellow Americans. And if we are going to make any mistakes, if we are going to err, it should be on the side of health and safety, I would think.

At the same time, we ought to be concerned about reasonableness and practicality and that sort of thing. What do you expect from the Congress? What do you expect from us? Mr. Cady?

Mr. CADY. Well, I think legislation that was passed is now getting to the point where the rubber meets the road. And while we have worked very closely with FDA and I think we have made great progress in terms of looking at their regulations and they have been forthright in dealing with industry on this, but I think it is an opportunity for us to be able to inform you as to how this legislation is progressing in terms of implementation.

And now, we are reaching some of the areas where practicality, in terms of doing commerce, are being affected, and I think each of us in our own way has explained what that is.

Mr. BILIRAKIS. And you have all done a great job, particularly in a short period of time.

Mr. CADY. We are dealing with the regulatory process, and we just want FDA to reconsider a lot of the areas that we raised today, I believe, and to see if there are workable ways to achieve what needs to be achieved without affecting commerce in a manner that is not only not economical, but is just unreasonable in some areas.

Mr. BILIRAKIS. You would suggest, what, a delay in the full enforcement date?

Mr. CADY. I think the enforcement date is going to be an interesting day. And we have talked about percents of inspections this morning. And I think we really—it hasn't happened yet. And if we are worried about it now, I am not sure what is going to happen on the 12th or the 13th. I am not sure we need a time postponement here, but as I talk with Secretary Thompson and FDA Commissioner McClellan at the time and I said, you know, on the 13th, we can't have all of the trucks in the world stopped at the border.

The food industry has got to continue. And I think it is a matter of using common sense and practical approaches trying to get through the first months of this new process and procedure. It has got to start some time, Mr. Chairman.

And I just think it behooves FDA to understand that a practical approach and common sense is going to be the way they enforce this in the beginning.

Mr. BILIRAKIS. You said it well.

Do you all have something very significant to add to it.

Mr. CLARKE. I would like to add that August 12, the penalty phase of the Bioterrorism Act is also being implemented. And I think the Agencies ought to devote more resources to protecting the citizens of the United States rather than being an enforcement Agency in penalty situations.

There has been little feedback coming back to the industries on really how the system is working, what its flaws are, how to address it. We all have concerns that, come August 12, there could be serious impact economically and physically on our infrastructure. Can we say categorically this will happen? No. But we are assuming, without some feedback from the Agencies on where our

problems lie and how to address them, there is no way we can address those in an adequate time before August 12.

We would ask the Congress to consider postponing the August 12 penalty phase of it, at least until such time as industry can adjust to the proper requirements based on our hope of an advanced educational program.

As far as brokers are concerned, being the front line, we are finding a lot of operational programs that are not being addressed properly.

Mr. BILIRAKIS. Is there—forgive me for interrupting, is there a specific date? Might you not come back?

Mr. CLARKE. We would like to see the program put into effect so we have feedback for a 6-month period and then open it up again for another 60-to 90-day comment period by trade. We want to work with the Agencies as best as we can.

The system itself right now is slightly flawed. It is not something that needs to be thrown out and started over. We need to make sure this isn't going to impede international trade and defeat the very purpose that it was put into.

Mr. BILIRAKIS. As I understand it, the staffs, Mr. Ford from the other side and on down from our side and I am not even going to try to pronounce his name, have been working really earnestly on this together to have a meeting of the minds. I would hope that we are not talking here an either/or kind of a thing, as I said earlier to Mr. Brown, that there must be something in between that can be done, that can be helpful and, at the same time, be consistent with our concern, all of our concerns, regarding the health and safety of our consumers.

Having said that, I yield to Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

Testimony from a number of you mentioned concerns with the prior notice requirement. Couple of them certainly sounded like they could be addressed administratively.

Mr. Clarke, if I could start with you. You mentioned, under current regulations, if a shipment is refused entry because of a problem with prior notice submission, FDA informs the carrier about the problem and not the person who submitted the prior notice. Looks to me like the law is silent on the question of whom should be informed. I don't know whether FDA has made the right call on that, but it sounds like that is an example of an issue that could be addressed administratively. Is it true that we could resolve that?

Mr. CLARKE. Yes, that is correct. Just the comment that I put in there of switching the date from arrival to entry would solve many of these operational problems, and it is something the committee may wish to consider. It does not jeopardize the security of the cargo. It is under Customs and Border Protection's full authority. Cargo cannot move forward, entry cannot be made.

Again, it does alleviate some of the penalty situations and devote more resources to actually looking at the goods and determining what is admissible and not admissible, rather than trying to penalize legitimate food importers.

Mr. BROWN. Mr. Cady, give me your read, if you would. FDA requires that a prior notice submission include the registration num-

ber for the facility that produced the product. This goes beyond what the law requires. Would you give us your comments on that and the ability for the Agency?

Mr. CADY. We are talking, I think, about registration numbers, companies registering obviously. If I could say about the 400,000 facility number that we have talked about at this point—I think that is a high number—and as FDA has gone through these regulations and exempted certain facilities, I think that number becomes lower.

And so, not knowing what the final number is, I do believe though we need to obviously have more education and overt action on the part of the Agency relative to making sure that companies know they have to register, and that is going to take time, sir.

Now, as far as the lot production number for traceability or whatever use we were talking about earlier, today, as I stated, you know, when we have a problem with a product, let us say it is, I don't know, a carrot product, as an example, you go in and remove all of those—all of the product itself. You don't look at lot numbers or purchase order numbers. You take it all off the shelf when there is a potential issue or a known issue. That is an easy way to do it and it is an awful lot more—it is a quicker way, I should say, to do it.

And the statute does—the statute does give manufacturers flexibility relative to how to account for these products. Now, again, the lot product is not the way to do it, the way in which FDA has proposed because, as my friend down the road here said, the lots get mixed up—not mixed up, they are just—yesterday's production is combined with tomorrow's production. It is all put on a truck that stops and drops off potato chips someplace. They are all commingled, and it is not an efficient way to pull something back. So I think that there are ways to do it, and we have a good system in effect right now for recalls, and I think FDA ought to be using that as the premise of their actions, sir.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman.

I appreciate this hearing because it addresses, I think, a lot of the concerns that many of us had moving into this debate, homeland security and bioterrorism and food safety issues, and then how to expeditiously move product to processing to stores to tables and in a manner in which we know is safe and sound, but also still efficient.

And what I am hearing, I think is that there is still an unknown, what is going to happen in August. Is it safe to say that—and, of course, when there is an unknown, that raises stress, because we might not have problems, but we could very well, because I am hearing there is a lack of communication as far as what is going to be expected and what are, from the FDA, especially with this and some of the things I mentioned in the opening statement. Am I on the right track here?

Ms. STOUT. If I could jump in here, I think the problem we are trying to get at the interim final rules on prior notice, the comment period closes July 13. The enforcement period starts mid-August. But if FDA is going to listen to any of the concerns that we have

voiced in this, until they issue the final regulation, which isn't inspected until next year some time, we have no relief.

And some of the things that they are doing—Mr. Brown asked the question here—the statute that was passed by Congress does not require that a registration number accompany a prior notice. That is a step beyond that the FDA has gone to and that is creating problems for us because, in many instances, that is not available.

Mr. CLARKE. Along those same lines, I would like to add, the way the regulations have been promulgated, it is based on individual transmission for each line item that is being transmitted into FDA. If you have a shipment coming in across the border with multiple line items, any one of those items could basically stop that shipment going forward. We do not have information coming back from the Agencies, either Food and Drug or Customs, in an adequate form for us to address if there is a problem or if there is not a problem. That has to be addressed before they can go into a final phase.

Mr. SHIMKUS. Did anyone address the issue of the perishability of products and the time sensitiveness of going across the border?

Mr. FRENCH. What we have experienced in some border crossings involves the FDA's indicating that they would like to sample product or taking their time to make a sampling decision. And when you are dealing with perishable product that has been slowing the process of crossing.

Mr. SHIMKUS. I know, in homeland security aspects, I know what we are trying to do with immigration issues is push our perimeter out. If we can get a good certification and evaluation of the processing facility that is going to be imported from, then, in essence, label that product as safe once it leaves, then you should be able to expeditiously move it through the border crossing. Is that what I am hearing?

Mr. FRENCH. I believe FDA guidance that predates 9/11 suggested that companies that are purchasing product know their suppliers and that measure of assurance, knowing who you are buying from, is certainly one of those things.

Ms. STOUT. That is one of the things that GMA has done. We have sister trade associations around the world, and we have been telling them, from the beginning, "Heads up, this is coming. This is what you are going to need to do to comply. You have to register. You can't get in the country."

You talked about the perishable. One of the things—and I think it has to do with the resource issue—is that there is a Customs inspector at the border at all times. There is not an FDA inspector. And what we are running into is, some of our products that are coming in—and an example is yeast, which doesn't stay a long time. If it arrives, you know, at 7 o'clock on a Friday night at the Canadian-American border and Customs allows it in because the prior notice is complete but he can't release it until an FDA inspector approves it and that may not be until noon on Monday, that truck of yeast is gone.

Mr. CLARKE. We are experiencing a situation, if you are using the Food and Drug prior notice system interface which has limited capacity, there is no direct link between that system and the custom system as far as the inspection arrival of the cargo. A hard

copy piece of paper has to be presented by the carrier to the Customs inspector at that time, circumventing all automated systems that are in place. It is not a very effective system and needs to be revised and looked at.

Mr. CADY. If I could add one thing, sir. In teaching the regulations as they stand today around the world, our organization has found—I mean if you go to Thailand and go to Singapore and Vietnam and a lot of people that bring food into this country, you have to understand what they are thinking and what they are trying to understand. They don't know if they have to register, and we are trying to explain it to them. They don't understand the border issues they are going to run into.

And for fresh product that is coming in overnight, seafood, et cetera, it presents a huge problem not only from a communications perspective, but more of an understanding perspective. So the industry has taken on an awful lot of this in terms of going out and educating different suppliers and partners around the world so this commerce thing that we have is going to continue to flow when this all goes into effect. And I think that is something very important.

One other thing that I could clarify, Mr. Brown's question if I could, just a second, on prior notice, is that the Bioterrorism Act doesn't require that. And more importantly, FDA needs to look at how do we make this system work efficiently and effectively right away. And the prior notice does not add to that. And in many cases, we can't find the registration numbers and the information needed to put on the prior notice certification, especially from countries outside of ours.

Mr. SHIMKUS. I want to thank the chairman for holding this hearing.

I hope the FDA kept their staffer here. And I would encourage them to get the stakeholders together, and let us resolve some of these conflicts, and I yield back.

Mr. BILIRAKIS. Hopefully it can be solved among you. Let's see.

Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. And again, I appreciate you calling the hearing.

Mr. Clarke, your testimony expressed concerns about the prior notice requirements and specifically the 5-day requirement. The law actually says that prior notice can occur more than 5 days and in advance, and the notice most be received within that 5-day window. Does that clarification in the law have any impact on the timing or your concerns about the timing?

Mr. CLARKE. The way the systems have been developed, though, it is impractical to do it 5 days prior because of the Customs and Borders protection requirements of transmission of entries. The only alternative you have to do that is to go through the interface system within the Food and Drug, which has been proven to be very ineffective and very time-consuming.

Mr. GREEN. Well, do you think we need to change at all then to——

Mr. CLARKE. There is no risk of security that we can see by extending that date beyond the 5-day requirement. In fact, through the Customs Container Security Initiative, they are actually screening merchandise and gaining information 24 hours prior to

the cargo being loaded on its conveyance to the United States, which in turn gives them an even more adequate chance to look at cargo and determine what is admissible and not admissible.

Along the same line, there has to be some coordination and harmonization between the two Agencies. A lot of data that is being transmitted under that phase of security could also be utilized by Food and Drug and making a prior determination on spot checking, whatever needs to be done to protect the consumer.

Mr. GREEN. Well, and I agree, and like I said, with an international port and air cargo, it is important we have as much coordination as we can. And that is why we might need to look at changing the statutory law that gives them that ability, along with other things that at our hearings and other hearings we will have.

Mr. Saunders, your testimony indicates that more than 80 percent of the food safety activities are formed at the State and local level, and we learned from our first panel that only about 2 percent of the food imports are actually inspected, and these inspections are based on the risk assessments. And from your perspective, representing both State and local officials, are you satisfied with the level of inspection at our borders? And other than increased Federal, State and local coordination, what can the Federal Government do to ensure that the food safety entering our harbors? And have you shared your views with the FDA and Customs? And I will just give a side line, being to the border—in Texas—a number of times with Mexico, I have found that our State border inspectors have a great deal of information to share. And I would hope there is only about a 50-foot separation between them and Customs in some cases. I would hope that there would be that information-sharing between the local and State.

Mr. SAUNDERS. There is significant information-sharing between the local and States and the Federal partners. You know, as far as the 2 percent coverage that the Federal Government is able to provide with respect to imports now, AFDO has believed for some time that that is not adequate and that there are ways to deal with that.

Some suggestions that have been made are for the FDA to focus more on import issues and rely on the States and localities to handle the domestic issues. There are things, such as memorandums of understanding with other countries, as I mentioned during my presentation, some foreign inspections of food establishments by FDA, and I think there are certainly other ways that those issues could be addressed so that there is a greater oversight of the products that are coming across our borders.

Mr. GREEN. Okay. Now, I think, from the first panel and knowing what is happening in my own area, I think a lot of that is being done, but, again, hopefully, it could be systemic and not just in certain ports, or it would be all through the—all around the country.

Mr. SAUNDERS. Yes, sir.

Mr. GREEN. Mr. Chairman, I appreciate the time.

Mr. BILIRAKIS. Mrs. Capps.

Mr. CLARKE. Might I add to that just one brief comment to that also? We have a layered approach to the security in this United States. We have Customs and Border Protection, who are doing quite a good job of screening cargo coming in through risk analysis.

Even though you may say 2 percent is only being looked at, technically every single piece of merchant cargo coming into the United States, whether it be food products or consumer products, is actually being screened by Customs and Border Protection under the risk-analysis procedures.

Mr. GREEN. And Mr. Chairman, I know I have taken my time, but I know that is true with the container for general cargo, too, that you are using the law enforcement techniques. You know, we are doing it. But I think our goal is to increase those percentages.

Mr. CADY. Mr. Chairman, Mr. Green, if I could just say one thing. We have—we talk about the borders and things come into the borders, but remember, we do a lot of food production within this country. And there are food safety systems in effect and food security systems in effect that compliment the border and the FDA and the AFDO and all the rest of the inspectors that we deal with.

And these food safety and food security systems, we spend millions and millions of dollars on ourselves protecting our brands and our food so there is a lot being done by the industry itself in addition to what these regulations——

Mr. BILIRAKIS. Can you share some of that information with us?

Mr. CADY. I will be happy to, sir, and can I provide that for the record for you?

Mr. BILIRAKIS. Yes. If you could provide that for the record for us we would appreciate that very much.

Mr. CADY. Be happy to do so sir.

Mr. BILIRAKIS. Thank you.

Mrs. Capps.

Mrs. CAPPS. I thank you, Mr. Chairman.

And according to your testimony, Mr. Saunders, the H.R. 7699—2699, sorry, whichever it is, 2699 would have quite an impact on State food and safety regulations and even on our Nation's efforts to secure our food supply. This is the National Uniformity For Food Act.

In my home State of California, as you may well be aware, we have very vigorous food safety and labeling laws which leads me to be very concerned about this legislation, and from your testimony, it sounds like this bill, if enacted into law, would really gut California safety laws. Is that true? And would you comment briefly?

Mr. SAUNDERS. AFDO has been following that legislation for quite some time, and we have done an awful lot with respect to trying to educate States and localities about the language in that legislation. We have met with attorneys who have reviewed the legislation. We have had numerous States—and I believe the most recent count there were 12, are 12 States—that have had their attorneys look at that legislation. And they have all agreed that there are some very gray areas in that legislation that could have a very negative impact on these States and localities' abilities to operate effective food safety and security programs.

Ms. CAPPS. Well, you also, to make it more national in scope, I would like you to expand on the kind of comments that you made around the fact that this would be a national—it would be costly to our Nation in effect because of the interconnection between the State and Federal regulations. I guess on how much—it simply

said that the Federal Government kind of relies on the States' enforcement, and therefore, enacting this law would have—would affect our national budget as well.

Mr. SAUNDERS. Yes, we believe that it would. We—there is a very cooperative integrated food safety and security system in this country that involves Government Agencies at all levels. And that system has been in place for years. It has been improved upon for years, and if the States and localities lose their authority to enforce their laws and regulations, particularly with respect to adulteration—and when we are talking about terrorism that is what we are talking about—then the Federal Government is in a position to where they may have to pick that amount of work up.

And based on the survey that we have done and the amount of work that the States and localities are able to perform, it has been estimated that it could cost the Federal Government $500 million to replace the infrastructure that already exists among States and localities and to perform the number of inspections that they currently perform.

Mr. BILIRAKIS. Would the gentlelady yield?

Mrs. CAPPS. I will yield. But let me understand, that you see a direct connection to our terrorism readiness—I mean, this bill is about security. And if we enacted the law, this bill into law, and didn't make up for the cost, then we would be jeopardizing our national security in food safety.

Mr. SAUNDERS. Yes, ma'am.

Ms. CAPPS. I am going yield to the chairman.

Mr. BILIRAKIS. Let me just ask, Mr. Saunders, have you made an effort to communicate with the authors of that legislation?

Mr. SAUNDERS. Yes, sir.

Mr. BILIRAKIS. You have?

Mr. SAUNDERS. Yes, sir.

Mr. BILIRAKIS. And have you discussed this with them and your concerns?

Mr. SAUNDERS. Yes, sir.

Mr. BILIRAKIS. AFDO's concerns? You have? So they are aware of them?

Mr. SAUNDERS. Yes, sir.

Mr. CADY. Could I just add something, and then I would like to defer to my compatriot here, Ms. Stout?

Ms. CAPPS. Surely.

Mr. CADY. From the National Processors' perspective, we have reviewed that legislation pretty in depth. And we don't see the concerns that AFDO has expressed on that particular part of the issue, on that particular part of the bill.

Mrs. CAPPS. Which part? Excuse me, because there are a few different standards.

Mr. CADY. Well, I think there is a statement, ma'am, that talks about, if the uniformity bill were to pass, that it would destroy—or I am not sure the adjective being used—but it would essentially——

Ms. CAPPS. Would impact.

Mr. CADY. Adversely, the State authorities relative to their position.

Mrs. CAPPS. Right. But if one set of regulations is more stringent and in depth or however you want to describe it and there is a laxness or a lowering of the standards, it is going to be——

Mr. CADY. Well, I don't think the standards are lowered.

Mrs. CAPPS. Well, then you disagree.

Mr. CADY. We disagree. But I would like to have Susan talk about that.

Ms. STOUT. Yes, if I just may comment. I mean, this H.R. 2699, if you read the legislation, it does not have any effect at all on any State food inspection programs. It does not have any effect on any enforcement authorities enjoyed by the Federal, State or local.

The GMA has reached out since 1998, communicating with those who had concerns about the issue, including AFDO. We—there are many changes that were made to the provision, at their request, to make sure that, once the bill is enacted, there is a nice seamless cohesion that takes place. There is no cost to the——

Mrs. CAPPS. Excuse me?

Mr. BILIRAKIS. The gentlelady's time is expired.

But look. That is a separate piece of legislation. It will be subject to hearings. We will have the opportunity to go into the pros and cons and that sort of thing. I don't think we need to go any further.

Mrs. CAPPS. Well, I just want to—I know I have used my time, but I did yield to you.

Mr. BILIRAKIS. Well, I took about 20 seconds. But go ahead.

Mrs. CAPPS. The Federal Government often looks at States differently than States do, and I think, in the House, we sort of try to juggle those sometimes competing, hopefully not competing, interests, and I would—I believe we need to have further discussion in this area.

Mr. BILIRAKIS. And we don't—I don't think we should be predeciding on some of these things either. That is what hearings are all about.

The gentlelady's time has expired.

All time has expired.

I want to thank you. I would ask, maybe, one final question if I may. As against delaying the enforcement date from August 12 to a later date, is it—would it be reasonable—and I don't want to take 5 minutes on this—but would it be reasonable—and maybe you want to respond in writing—would it be reasonable to—so there are some areas where maybe enforcement, immediate enforcement, August 13 enforcement could or might take place, and other areas that possibly maybe should remain in the flexible enforcement category. Very, very quickly, though, because I don't want to take much time on that.

Mr. CLARKE. Yes, that is a possibility. But, again, the systems that are in place do not give us that luxury to have that. It requires, to be coming in on October 12, edits to be turned on, systems to be shopped, shipments to be stopped at that date, and I am not sure the Agencies have the capability of extending, on a partial basis, either all or nothing. But the Agencies themselves would have to address that.

Ms. STOUT. I also think, Mr. Chairman, it would be incredibly helpful if the Agencies could give us feedback on what the problem

has been with the prior notices that have been submitted and have been——

Mr. BILIRAKIS. The Agency is right behind you.

Ms. STOUT. They have been terrific.

Mr. CADY. Mr. Chairman, I think the thing that would be most helpful would be to, perhaps, not implement the penalty phase. I think that is probably the most important thing at this point because of the need for understanding and, as I said earlier, the need for a practical implementation of this.

The Agency and the Department of HHS have assured us, me, that they will have a practical commonsense implementation. It needs to start, but they need to be flexible until they, themselves, understand what the impact of these regulations are going to be on their workload as well as on commerce and the Agencies' ability to do something. So I think those two things—I don't think you win anything by pushing it down the road 6 months. But I do think flexibility, which the Agency does have, can be utilized and the penalty phase perhaps implemented at a later date.

Mr. BILIRAKIS. Thank you, Mr. Cady.

Mr. Brown, anything further?

All right. This hearing—again, as I said earlier, any further ideas or suggestions or recommendations or whatever, we always will welcome them. It is important, the more information we have available, the better job that we can do if we do directly get involved as far as this area is concerned. Thank you. The hearing is adjourned.

[Whereupon, at 12:03 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

NATIONAL FOOD PROCESSORS ASSOCIATION
August 9, 2004

VIA Email

The Honorable MICHAEL BILIRAKIS
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515-6115

DEAR CHAIRMAN BILIRAKIS: I am writing to provide my responses to the questions you transmitted in your July 26, 2004 letter, which followed the June 25, 2004 hearing, "Implementation of the Food Security Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act." Please find my responses attached.

I again thank you for the opportunity to testify before the Subcommittee. If you have any questions regarding the attached responses to the Subcommittee's questions, please contact me.

Regards,

JOHN R. CADY

Attachment

RESPONSE TO FOLLOW UP QUESTIONS

Question 1) I would like to ask each member of the panel what steps their members have taken to help secure our food supply from terrorists.

Response: The steps taken by members of the National Food Processors Association (NFPA) to protect the food supply against terrorist attack include renewed attention to existing food safety measures and systems, such as Hazard Analysis and Critical Control Point programs, Good Manufacturing Practices, product quality and safety assurance programs, and ingredient/ingredient supplier specifications and monitoring, that contribute to ensuring food security has not been compromised.

While each food company and facility must tailor security measures to their unique situation, there are clear trends in the actions being taken by NFPA members. As information becomes available about possible threat agents, whether biological or chemical, companies are evaluating how these agents may respond during food processing and what measurement tools need to be developed for rapid detection. Many companies are using relevant guidance, including a manual prepared by NFPA and the Food Marketing Institute and general guidance from federal agencies, to evaluate security vulnerabilities with subsequent adoption of steps to mitigate or remove these vulnerabilities. The types of actions include stringent access controls to facilities, protocols for responding to suspected terrorist threats, background checks as permitted on potential employees, and security awareness training for employees. A growing number of companies are pursuing formal security plans. NFPA is committed to helping in this regard and is in a unique position among industry trade associations in that a security and emergency response expert has been added to the NFPA staff. The actions taken extend beyond security at company facilities to include working with suppliers to ensure appropriate security is in place throughout the supply chain. NFPA is facilitating and encouraging information exchange among our members as we move forward. However, specific plans and programs will continue to be kept confidential to ensure security is not compromised.

In addition to the voluntary security initiatives taken by our members, compliance with FDA's Bioterrorism Act rules is also a priority. NFPA's members supported passage of the Act and continue to recognize the importance implementation of the rules will have as part of the needed industry/government partnership to enhance the security of the U.S. food supply.

Question 2) I would like to ask the members of the panel about the prior notice requirement, and whether you believe the system can be fully operational by August, and what steps they would recommend to make the system more workable.

Response: While NFPA believes functioning systems for receiving and electronically evaluating prior notices will be operational by August, concerns remain. The most recent FDA compliance summary released in May 2004 indicates that, as of April 2004, "very few" entries had no prior notice. However, the FDA data shows there continues to be a large percentage of the total of approximately 150,000 prior notices received each month that would not be accepted under full enforcement of the prior notice rule. FDA notes specific data elements most frequently absent are carrier data and manufacturer's registration numbers. The lack of carrier identity is most notable for arrivals by road, which means shipments from Canada and Mexico. FDA's analysis concerns the completeness of prior notices and does not include assessment of the accuracy of the information provided, which makes it difficult to determine what other clerical or processing problems may be occurring. NFPA believes FDA's analysis indicates industry is making a good faith attempt to comply with prior notice requirements. However, there is a high likelihood of major disruptions at the Canadian and Mexican borders if full enforcement begins in August.

NFPA's suggestions, which have been communicated in comments to FDA, for steps that should be taken to make the system more workable are:

1. The discretionary enforcement period should be extended to December 12, 2004 and targeted education programs should continue to specifically address problems such as carrier data for cross border trucks.
2. A solution must be identified to accommodate entry of samples for research for which manufacturer's registration numbers cannot be provided.
3. Time frames between Customs and Border Protection and FDA should be integrated prior to the end of the discretionary enforcement period.
4. The prior notice interface system should be simplified and better technical assistance provided to submitters.

Question 3) Do you have a sense of what the registration compliance rate is for your members?

Response: NFPA believes that all member company facilities that clearly should be registered, such as processing facilities, have in fact registered with FDA. NFPA advised member companies to register facilities even if there was some uncertainty as to the applicability of the registration requirement. It appears our members have responded to this advice. NFPA continues to work with members to ensure compliance, as FDA further refines its interpretation of the registration rule, particularly with respect to facilities at which the holding of food is a minor and incidental activity.

Question 4) What more can be done to educate industry on the need to comply with the registration requirement?

Response: One of the most important steps FDA can and should take in continuing to inform the industry about the facility registration requirements is to respond in a timely way to questions that have been posed to the Agency regarding

the application of the rule. The response needed from FDA is the timely update of the guidance provided in the question and answers page that is published on the Agency's website. This guidance helps companies directly as well as supports ongoing education and assistance efforts such as those conducted by NFPA. While FDA recently updated its facilities registration question and answer document, only four questions were addressed during the six months since the document was last updated. Many more questions remain.

NFPA also supports FDA's ongoing use of its current enforcement policy, which emphasizes education, awareness, and allowing companies to come into compliance, except in those instances when full enforcement is needed. Under a flexible enforcement policy, FDA may be able to identify sectors or categories of facilities that merit targeted education efforts, either by the Agency or by industry. NFPA anticipates a need for ongoing education efforts, particularly for foreign facilities/companies.

Question 5) In your opinion how could the Food and Drug Administration build upon companies' current record keeping regiments and still meet the intent of the record-keeping requirement?

Response: The current record keeping regimens of food companies should for the most part satisfy the intent of having "one step forward, one step back" information available for the FDA under circumstances where there is a threat to the food supply. Food companies already have in place the ability to identify sources of food and food ingredients in the event of a product tampering or product recall. Within a company, business records (purchasing, sales and distribution) as well as the manufacturing and inventory records are sufficient to meet the requirements of the Act. We recommend that the role for FDA be limited to verifying that food companies have implemented such systems that reflect the nature of their businesses and that food companies validate that such systems are functional and effective. This verification and validation role for FDA will build upon the food companies records systems and provide assurance that FDA can obtain information quickly and efficiently to carry out investigations in the most timely and comprehensive manner possible.

Question 6) Some have raised concerns that the lack of FDA inspectors at every port 24 hours a day, seven days a week will lead to shipments being unnecessarily delayed at the border. Do you believe the December 2003 Memorandum of Understanding between the FDA and Customs that allows Customs officials to inspect shipments when the FDA is not present will eliminate this potential problem or are more steps required?

Response: The MOU between FDA and Customs and Border Protection (Customs) is critical to successful implementation of the prior notice provisions of the Bioterrorism Act; every port must have adequate coverage 24 hours a day, seven days a week. A larger concern is potential back up consequences to shipments that are in compliance, particularly to cross border truck traffic, when products are held or diverted to secured storage. Accommodations must be made to move non-compliant or questionable shipments quickly from traffic lanes. Like Customs, FDA should facilitate trade for low-risk shippers.

Question 7) Your organizations have both raised concern over the ability of companies to bring in competitive samples and how this impacts the ability of companies to perform research and development in the United States. Given that these products are usually bought at the retail level your companies would not have access to the manufacturer registration number. Have you voiced these concerns with the FDA, and if so what has been their reaction?

Response: NFPA has shared industry concerns with FDA both through written comments and in discussions with FDA officials. NFPA has indicated that the statutory language allows FDA the authority to provide an alternative solution that would identify the manufacturer without the specific registration information. FDA has acknowledged these concerns and has conveyed the view that: (1) FDA does not have the statutory authority to provide an exception for samples; (2) FDA requires the registration numbers to implement other provisions of the Bioterrorism Act; and (3) samples could pose a "risk."

Question 8) Has either of your organizations provided the FDA suggestions to address the problem of competitive sampling without compromising the integrity of the registration and inspection system of imported food products?

Response: Through comments filed on July 13, 2004, NFPA made the following recommendation:

"Because the statute does not mandate a manufacturer's registration number, a prior notice for food samples would be deemed legally sufficient using any of the following alternative solutions:

- FDA could provide an alternative prior notice in a simplified version (that does not require manufacturer registration numbers) for products that are shipped to the United States and not intended for public consumption or sale;

- The manufacturer's registration number could be replaced by other identifying information such as the manufacturer's name and address;
- The manufacturer's registration number could be replaced by the registration number of the importing manufacturer who is ultimately responsible for the shipment and final use of the product;
- FDA could require registration numbers for either shipper or manufacturer. This alternative would provide FDA with information to enable enforcement of foreign facility registration without imposing unnecessary and unobtainable information burdens; it would also allow a U.S. manufacturer to recall product to the United State when necessary without unnecessarily registering a "shipper" or allow U.S. companies to ship samples from sales offices abroad.

"At most, any of these alternatives would require only a simple technology adjustment to identify a specific shipment category: samples for research and development. The prior notice regulation could easily be amended to accommodate this change merely by addressing food samples as well as gifts in section 1.281(a)(6), to read as follows: If the article of food is sent by an individual as a personal gift (e.g., for non-business reasons) to an individual in the United States, or is imported as a sample for research and development purposes, you may provide the name and address of the firm that appears on the label under 21 C.F.R. 101.5 instead of the name, address, and registration number of the manufacturer."

INTERNATIONAL FOODSERVICE DISTRIBUTORS ASSOCIATION
August 9, 2004

The Honorable MICHAEL BILIRAKIS
Chairman
Subcommittee on Health
Washington, DC 20515

DEAR MR.CHAIRMAN: Thank you for the opportunity to present testimony before your panel on June 25, 2004, at the hearing titled: "Implementation of the Food Security Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act."

Attached you will find responses to your additional questions for the record. Please feel free to contact me if you have any further questions.

Thank you again for your consideration during my appearance before the Subcommittee.

Sincerely,

DAVID G. FRENCH
Senior Vice President, Government Relations

Attachment

FOLLOW UP QUESTIONS

Question 1) I would like to ask each member of the panel what steps their members have taken to help secure our food supply from terrorists.

Answer: IFDA members consider the safety and security of their products their most important responsibility. Companies in our industry have taken a number of steps to safeguard facilities including (but not limited to) fences, surveillance cameras, perimeter lighting, motion detectors, card-controlled access points, background checks and photo identification cards for employees. In addition, our companies strive to purchase products from known suppliers.

Question 2) I would like to ask the members of the panel about the prior notice requirement, and whether you believe the system can be fully operational by August, and what steps they would recommend to make the system more workable.

Answer: Our member companies have reported very few problems with the prior notice requirement.

Question 3) How are recalls conducted in the foodservice industry? How frequently do products need to be recalled?

Answer: Foodservice firms typically conduct one or two recalls per month. A recall is conducted when a restaurant operator, a manufacturer, or a distributor detects a health or safety issue. Foodservice companies work with their supply chain partners to identify the products involved and the dates the products were received and shipped. Then, a distributor will manually check for lot numbers of individual pallets and cases to verify that the correct products are withdrawn from commerce. When there is any doubt regarding which products are involved, companies err on the side of caution by withdrawing more product than necessary.

Question 4) If lot numbers are not used to identify products, how do operators and distributors know that they will remove the proper items from commerce?

Answer: Distributors do not typically use lot numbers to track product, because there is no standard format for lot number coding or placement on products and cases. Also, many distributors receive products on pallets that may contain four or more different lot numbers. Instead, most distributors track products using purchase order numbers. Lot numbers, however, can be useful in identifying specific products to remove during a recall; but this process often requires manual verification of lot numbers.

Question 5) Are UPC codes, or barcodes, used to track product?

Answer: Adoption of UPC codes is not widespread by foodservice manufacturers. Recent product surveys have shown that less the eighty percent of the cases in most foodservice warehouses carry a UPC code. Barcodes are, however, very useful; and many distributors assign their own internal system to products upon receipt so that these products can be tracked and quickly located within the distributors' operations.

Question 6) Wal-Mart and the Pentagon have announced ambitious plans to require their suppliers to use radio frequency identification (RFID) tags to improve efficiency within their distribution channels. What is the future of RFID in the foodservice distribution industry?

Answer: RFID is most likely the future for efficient warehouse and logistics management, and the foodservice industry is enthusiastic about the technology's promise. There are many hurdles to cross, however, before RFID will be widely used within our industry. Cost of the technology is one of the challenges. The chips are expensive, costing roughly $0.55 each; so RFID presently offers the most promise for high-value, low-volume products. Foodservice industry products, however, are typically low-value and high-volume. The technology has not yet been perfected, either. Tests of the current generation of technology show a 95% "read-rate." Since the cost of correcting errors can be quite high, the foodservice industry strives for accuracy rates that exceed 99.9%. As one example of the challenge of making RFID work for our industry, readers have problems tracking tags through metal and liquids, which are the packaging and contents of a large number of food products. Until these bugs have been ironed out, it is unlikely that most foodservice firms will experiment with the technology. Finally, it is important to point out that Wal-Mart's initiative will have little impact on foodservice distributors since foodservice distribution and retail grocery distribution are separate supply chains with few shared products.

Question 7) Mr. French, you said that the current time frame given to companies to produce their records is too short. Why would companies not be able to comply with the current time restraints? What would be a more reasonable time frame?

Answer: Most companies can and do retrieve their records promptly, but we remain concerned that the time is too short in view of the potential penalties. In foodservice industry contractual arrangements, for example, eight hours is the most common time allotted for record retrieval.

Question 8) You mentioned your concerns with the Food and Drug Administration's educational efforts on explaining why prior notices are deficient. Do you have any suggestions on how FDA can improve in educating industry on the information required and format of prior notices?

Answer: It would be useful for FDA to communicate with prior notice filers regarding what about their filed notices is deficient, and to do so before the period of full enforcement begins. It is certainly possible that prior notice filers, acting in good faith, but ignorance, are making errors in their notices. Better information from FDA now regarding deficiencies in filed prior notices will prevent needless and burdensome compliance problems later. Also, we suggest that FDA reopen the comment period on the prior notice rule after there has been a period of active FDA/CBP enforcement. In this way, if there are operational problems that arise once active enforcement begins, the food import community and FDA/Customs will have a channel of communication open to discuss and address these issues. This "real life" experience will allow for informed comments on the true workability of the prior notice rule. FDA would then issue a final prior notice rule thereafter.

Question 9) Do you have a sense of what the registration compliance rate is for your members?

Answer: We are not aware of any IFDA member that has failed to register, nor are we aware of significant numbers of unregistered companies among other foodservice industry firms. Since the registration requirement was enacted, we have worked to educate our members about the law. For example, IFDA staff members have presented educational briefings at industry conferences to reach an audience broader than our membership, and our association has invited senior FDA officials

to address industry meetings. Our association, however, only represents the largest 130 companies of an industry that has been estimated to be as large as 2500 firms.

Question 10) What more can be done to educate industry on the need to comply with the registration requirement?

Answer: We have explored a variety of avenues to educate and inform our industry about registration. Reopening the comment period after a period of active enforcement might yield more information about non-compliance and tools for reaching these firms.

Question 11) In your opinion how could the FDA build upon companies' current record keeping regiments and still meet the intent of the record-keeping requirement?

Answer: The goal of the record-keeping requirement is to enable the FDA to quickly and efficiently manage a product recall. The law does not require the FDA to reinvent the process, and there is no evidence that the current system of voluntary, cooperative recalls has failed.

Question 12) Some have raised concerns that the lack of FDA inspectors at every port 24 hours a day, seven days a week will lead to shipments being unnecessarily delayed at the border. Do you believe the December 2003 Memorandum of Understanding between the FDA and Customs that allows Customs officials to inspected shipments when the FDA is not present will eliminate this potential problem or are more steps required?

Answer: It is too early too tell what problems will be experienced when full and active enforcement is in effect. To date, our members have reported few problems with imports. As discussed above, the industry may benefit from an additional opportunity to submit comments once there is experience with full enforcement.

GROCERY MANUFACTURERS OF AMERICA
August 9, 2004

The Honorable MICHAEL BILIRAKIS
Chairman
Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

DEAR CHAIRMAN BILIRAKIS: Thank you again for the opportunity to appear before the Subcommittee on Health on June 25, 2004, at the hearing titled: "Implementation of the Food Security Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act."

My answers to the additional Subcommittee questions are attached. Please do not hesitate to contact me if you have additional questions or needs on this issue. As I stated during the hearing, food security is an all important issue to the Grocery Manufacturers of America and we stand ready to assist your further actions in this area.

Thank you again.

Sincerely,

SUSAN M. STOUT
Vice President, Federal Affairs

GROCERY MANUFACTURERS OF AMERICA RESPONSE TO FOLLOW UP QUESTIONS

Question 1) I would like to ask each member of the panel what steps their members have taken to help secure our food supply from terrorists.

Response: With over 140 members, GMA is sure you appreciate that we can't provide an exhaustive list of all the steps our members have taken. In general, they have revisited their physical security programs for plants, warehouses and other facilities; reviewed and upgraded where necessary traditional food safety, GMP and HACCP programs, from receipt of raw materials through processing, packaging and distribution; and have reemphasized employee screening and relations with suppliers, distributors and customers. Our members have also worked through GMA in at least three areas. First, in November 2001 GMA established Project Vigilance which collected from and provided to members best practices in the area of food defense and security. Second, with FMI (Food Marketing Institute), GMA has established Food Elert, a password-protected web-based system with which security experts from food manufacturers and food retailers can better communicate with each other in emergencies, and which GMA uses to provide information from DHA, FDA and USDA in a restricted way to members' food security experts alone. Lastly, at our members' request, GMA has been actively engaged in the Food Industry ISAC

since February 2002, and more recently in the development of the Food and Agriculture Sector with DHA, FDA and USDA.

Question 2) I would like to ask the members of the panel about the prior notice requirement, and whether you believe the system can be fully operational by August, and what steps they would recommend to make the system more workable.

Response: GMA has grave concerns about results if the prior notice system becomes fully operational in August of 2004. Although FDA has operated the prior notice system since December in an "educational" mode, companies that submit prior notices have not received from FDA specific feedback on notices. Thus, it is difficult, if not impossible—even for a company that is most dedicated to compliance—to know whether the prior notices that it has submitted over the last eight months comply with FDA's requirements and expectations. We are concerned that if full compliance begins in August, companies will only then learn about problems with prior notice and products will be denied entry. We suggest that FDA extend the educational phase of prior notice compliance and create a mechanism to provide feedback to prior notice submitters that is specific individual notices.

Question 3) Stout, what are the biggest problems you envision with the prior notice rule?

Response: The biggest problems with the prior notice rule will flow from FDA's insistence, at least thus far, on requiring the facility registration number to be a part of prior notices. As I explained in my testimony, registration numbers are not always available to persons legitimately importing products. For example, many GMA member companies routinely import samples—competitor's products or potential new ingredients—produced in facilities where the registration number is either not available or where the facility is not required to register. Requiring the registration number as part of prior notice—something that the Congress did not specify—will impede importation of samples and create a powerful incentive for companies to relocate R&D facilities to locations outside the United States. FDA could easily solve this problem by eliminating the requirement for the registration number for shipments of samples and in other instances in which it is not reasonably available.

Question 4) What are you most concerned about with regard to record keeping?

Response: FDA has proposed to require that lot or production codes be included in records to be maintained under the recordkeeping regulation. It is neither practicable nor necessary for records to include lot or production code information. When foods are delivered to retailers, the delivery persons do not have the capability to capture the lot or production code information as store shelves are stocked and restocked. Moreover, this information is not reasonably needed by manufacturers or by FDA. If problems arise with a product that necessitates its removal from distribution, manufacturers and retailers will remove all products, not just the product with the offending lot or production codes. It is simply more efficient to remove all of a product from distribution than to laboriously review the lot or production code on each product and to remove only those at issue. FDA should eliminate the requirement for lot or production codes as part of the bioterrorism recordkeeping regulation.

Question 5) Are FDA and Customs doing a good job of coordinating with one another?

Response: Coordination between FDA and Customs is markedly improved. There is still ample room for improved coordination. In addition, there remain some instances in which FDA prior notice requirements and Customs notice requirements are not compatible. The agencies should work to eliminate those inconsistencies.

Question 6) Do you have a sense of what the registration compliance rate is for your members?

Response: GMA is confident that its members are fully aware of the registration requirement and in compliance with it. GMA has devoted considerable resources to providing educational materials and advice to its members on registration and other bioterrorism requirements.

Question 7) What more can be done to educate industry on the need to comply with the registration requirement?

Response: It is difficult to suggest specific educational initiatives that would be likely to increase the registration rate without the benefit of an analysis of the registration database as compared to what FDA expected. We understand that far fewer facilities have registered than was assumed would be the case, but we do not know whether that is because the initial assumptions were faulty or because there are large numbers of facilities that are subject to the registration requirement, but which remain unregistered.

Question 8) In your opinion how could the FDA build upon companies' current record keeping regiments [sic] and still meet the intent of the record-keeping requirement?

Response: Under the FDA recordkeeping proposal, companies would be able to continue to use existing recordkeeping systems so long as those systems capture the information required by FDA. If FDA were to eliminate the requirement for lot or production codes, we are confident that GMA member companies will be able to comply with the recordkeeping requirements without great difficulty.

Question 9) Some have raised concerns that the lack of FDA inspectors at every port 24 hours a day, seven days a week will lead to shipments being unnecessarily delayed at the border. Do you believe the December 2003 Memorandum of Understanding between the FDA and Customs that allows Customs officials to inspected shipments when the FDA is not present will eliminate this potential problem or are more steps required?

Response: If FDA is able to train adequately the Customs personnel who will inspect when an FDA inspector is not available, we believe that most problems will be eliminated. Absent considerable additional resources for FDA to hire and train more inspectors, we believe that the 2003 MOU is the only practical way to address the problem. It is important that both FDA and Customs understand that prompt review of products offered for importation is critical to the food industry and to consumers who rely on the availability of a wide variety of food.

Question 10) Your organizations have both raised concern over the ability of companies to bring in competitive samples and how this impacts the ability of companies to perform research and development in the United States. Given that these products are usually bought at the retail level your companies would not have access to the manufacturer registration number. Have you voiced these concerns with the FDA, and if so what has been their reaction?

Response: GMA has provided FDA with a detailed description of its concerns with the requirement for registration numbers for prior notices that cover competitive samples. We have also discussed the matter on several occasions with FDA representatives. As of yet, we have received no indication that FDA is favorably disposed.

Question 11) Has either of your organizations provided the FDA suggestions to address the problem of competitive sampling without compromising the integrity of the registration and inspection system of imported food products?

Response: GMA has provided FDA with a very specific suggestion to address the competitive sample problem, without compromising the integrity of the registration and inspection system for imported foods. We have suggested to FDA that they permit a prior notice to indicate that: (1) the product to be imported is a sample; (2) the registration number is not available; and, (3) the product is destined for an R&D facility. We have further suggested to FDA that it would be entirely appropriate for FDA to increase the likelihood of inspection and examination of products covered by a prior notice where the products are characterized as "samples." Moreover, FDA could well impose a quantity limit on sample importations in order to further ensure that the characterization of a shipment as containing samples is not abused. More generally, we do not agree with FDA that requiring the registration number is always an important element of prior notice or that FDA can rely on the fact that a person who has a facility registration number is a legitimate importer. Some facility registration numbers will become known, either through carelessness or something more nefarious. FDA should no more assume that possession of a registration number indicates legitimacy than any law enforcement officer should assume that knowing a social security number is proof of one's identity.

Additional comments for the record:

GMA would like to take the occasion of responding to the Committee's supplemental questions to take strong exception to the testimony from representatives of the Association of Food and Drug Officials ("AFDO") concerning H.R. 2699, which would provide for national uniformity in food labeling and safety regulation. AFDO asserts, without any basis in fact, that the uniformity legislation would undermine efforts to ensure the security of the food supply. Not only were these comments outside the scope of the hearing, but also, they were blatantly false. To the extent that the uniformity legislation has any bearing on food security, it will help to enhance food security. One of the challenges of homeland security is to apply the available resources of government and the private sector in the most efficient fashion possible. Requiring that the states enforce the same requirements as those established by FDA—which is what the uniformity legislation would do—is consistent with that principle. It is wasteful and not consistent with food security to have inconsistent requirements at the federal and state levels. Food safety and food security require that all regulators enforce a consistent set of requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Michael Bilirakis
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

OCT 7 2004

Dear Mr. Chairman:

Thank you for your letter of July 26, 2004. The Food and Drug Administration (FDA) appreciated the opportunity to testify before your Subcommittee at the June 25, 2004, hearing on "Implementation of the Food Security Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act." With your letter, you submitted eight questions in follow-up to that hearing. FDA's responses to the questions are enclosed.

Thank you for your leadership in the enactment of this landmark legislation. We look forward to continuing to work with you and your staff on its implementation. If you have further questions, please let us know.

Sincerely,

Patrick Ronan

Patrick Ronan
Assistant Commissioner
for Legislation

Enclosure

cc: The Honorable Sherrod Brown
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-3513

FDA Responses to Questions Submitted by Chairman Michael Bilirakis Following June 25, 2004, Hearing on Implementation of the Food Security Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act

QUESTION:

1) Dr. Crawford, can you generally explain the many steps FDA has taken to upgrade food security in this country and what more do you see that needs to be done?

RESPONSE:

If a terrorist-related outbreak occurred in the United States, the Food and Drug Administration (FDA or the Agency) would work closely with Federal, state, and local authorities to identify the problem, investigate, and get the contaminated products off the market quickly. Here are some examples of how the Agency works to safeguard the food supply:

Prevention and Surveillance: After September 11, 2001, FDA conducted food supply vulnerability assessments. The Agency also issued guidance documents on security measures that the food industry can take to minimize the risk that food will be subject to tampering or other criminal actions. The guidances are aimed at food producers, processors, transporters, importers, retailers, food service establishments, and cosmetic processors. The Agency has also issued a separate guidance document for the milk industry on the kinds of measures that operators of dairy farms and others in the milk industry can take to minimize the risk that fluid milk under their control will be subject to tampering or other criminal actions

FDA is working with the United States Department of Agriculture (USDA) and other Federal and state agencies on the Electronic Laboratory Exchange Network (eLEXNET), the first integrated, web-based data exchange system for sharing food testing information. It allows multiple agencies engaged in food safety activities to compare and coordinate findings of laboratory analyses. This capability enables health officials to assess risks and analyze trends and provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. We are continuing to increase the number of participating laboratories.

A critical component of controlling threats from deliberate foodborne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for a variety of biological, chemical, and radiological agents. To increase surge capacity, FDA has worked closely with the Centers for Disease Control and Prevention (CDC) and USDA to establish the Food Emergency Response Network (FERN). Once completed, FERN will encompass a nationwide network of Federal and state laboratories capable of testing the safety of thousands of food samples, thereby enhancing the nation's ability to swiftly respond to a terrorist attack.

Protecting Imports: The Agency is improving its efforts to ensure the safety of the rising volume of imported food shipments that arrive in the U.S. each year. With additional funding for counterterrorism, FDA has hired more than 655 new field personnel. Of these, 635 were hired principally to address food safety and food defense issues, primarily at the border. With these additional field employees, we have expanded FDA's presence at ports of entry from 40 ports to 90, increased surveillance of imported foods, increased domestic inspections, and enhanced our laboratory analysis capacity.

The Agency has also updated its laboratories to handle the increased number of food samples that need to be tested for potential contamination by terrorism. We have embarked on an ambitious research agenda throughout the Agency to address potential terrorist threats. There are more than 90 active FDA research projects on the development of tests and sampling methods to quickly detect contaminated food. A major focus is on developing rapid test kits that can be used to quickly inspect food at U.S. ports of entry.

Four Major Regulations: As you know, Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) provided the Secretary of Health and Human Services with new authorities to protect the nation's food supply against the threat of intentional contamination and other food-related emergencies. FDA is responsible for implementing these food safety and food defense provisions. These new authorities will help improve our ability to act quickly in responding to a threatened or actual terrorist attack, as well as other food-related emergencies.

FDA published the final rule to implement the Administrative Detention provision of the Bioterrorism Act on June 4, 2004. FDA published the Interim Final Rules (IFRs) on the Registration and Prior Notice provisions on October 10, 2003. FDA will continue to work diligently on the Registration and Prior Notice final rules which we expect to publish in June 2005. We are in the process of finalizing the Recordkeeping rule at this time. In addition, FDA is working on guidance for industry on other provisions of the Bioterrorism Act such as section 308 – Authority to Mark Articles Refused Admission into the United States, section 309 – Prohibition Against Port Shopping, and section 304 – Debarment for Repeated or Serious Food Import Violations.

QUESTION:

2) FDA has announced full enforcement of the prior notice requirement will begin in mid-August this year and that there are a number of prior notices submitted since December 2003 that are not complete or otherwise inadequate.

What are FDA's plans, beginning this August, to deal with food shipments that do not have a fully compliant prior notice? Can we expect gridlock at the borders with Mexico and Canada as trucks carrying food are not allowed to come into the United States?

RESPONSE:

FDA, in conjunction with Customs and Border Protection (CBP), has been carefully monitoring and evaluating the status of prior notice submissions. On August 12, 2004, the agencies issued a revised compliance policy guide (CPG) that provided that FDA and CBP should typically consider not taking any regulatory action through November 1, 2004, for the following violations: the registration number submitted for the manufacturing facility is inaccurate or is invalid; the registration number for the shipper is not provided; the airway bill number or bill of lading number is not provided or is invalid; and the name and address of the ultimate consignee is inaccurate because it contains the name and address of the express consignment operator or consolidator instead of the ultimate consignee. For these violations, the two agencies generally will continue to exercise enforcement discretion until November 1, 2004, unless the violation reflects a history of the repeated conduct of a similar nature by a person who had been notified of such violations. We fully expect the vast majority of shipments to otherwise be in compliance and thus do not expect gridlock at the border.

QUESTION:

3) Dr. Crawford, the information the person filing the prior notice has to supply includes shipper and manufacturer details, such as the manufacturer's FDA registration number. There are many cases where this information is not available.

How will manufacturers and research laboratories be able to submit prior notices to get samples of food into the United States when the information needed to file a prior notice cannot be obtained?

RESPONSE:

FDA concluded in the Prior Notice IFR that samples of food, including trade and market

research samples, are subject to the Prior Notice IFR as they are "articles of food imported or offered for import" as stated in section 801(m) of the Federal Food, Drug, and Cosmetic (FD&C) Act (Volume 68, *Federal Register* (FR) page 58993). However, not all samples require a prior notice submission. If the samples are items that are in such early stages of research and development that they cannot yet be considered food under Title 21, *Code of Federal Regulation* (CFR) section 1.276(b)(5), they would not be subject to prior notice requirements. An example of such an item is a substance being tested for possible preservative qualities before being tested in any food (68 FR 58993). Similarly, if the sample is in a form that is not an article of food, such as slurry of lettuce for pesticide analysis (as opposed to a head of lettuce) or a juice already packaged in a sterile sample container for heavy metal analysis (as opposed to a can of juice), prior notice requirements would not apply.

We received comments to the prior notice docket expressing similar concerns about the inability to acquire registration numbers when importing samples for testing. As we noted in our response to the second question, FDA and CBP recently issued a revised CPG that states that FDA and CBP will typically not take any regulatory action through November 1, 2004, when the registration number is inaccurate or invalid. Moreover, under the CPG, if food is imported for quality assurance, research or analysis purposes only (and not for human or animal consumption and not for resale), then FDA and CBP will typically not take any regulatory action when the registration number of the manufacturing facility is not provided. We will continue to consider these issues while we draft the final rule.

QUESTION:

4) Of particular concern are cases when a U.S. manufacturer or laboratory has purchased small quantities of food at stores in foreign countries to bring to the United States for research and development purposes. Under the rule, these foods would be stopped at the border because all the needed information, particularly an FDA registration number, would not be available.

   What will be the impact on the food industry in the United States if research and development samples are not allowed to be imported? Will this force companies' R&D divisions to move, e.g. to Canada?

RESPONSE:

Please see our response to Question 3. Under the revised CPG, FDA and CBP should typically consider not taking any regulatory action for certain research and development samples that are imported or offered for import without identification of the registration number assigned to the manufacturing facility. This should allow the U.S. food industry to continue to import research and development samples for quality assurance, research, and analysis purposes.

QUESTION:

5) [There was no question 5 in the original document]

QUESTION:

6) We understand that separate Prior Notice filings are required for, say, an 8 oz. can of tuna and a 12 oz. can of tuna. Obviously this means twice as much work for the food importer.

   Can you advise why this information is critical for FDA's enforcement efforts? Couldn't the fact that the shipment contains both 8 oz and 12 oz cans of tuna be included on one Prior Notice filing?

RESPONSE:

Including information on both the 8 oz and 12 oz tuna does not require twice as much work for the submitter. Provided that the two sizes of food product are manufactured by the same facility and are included in the same shipment, after the required information is submitted for the 8 oz can, the only additional information that must be submitted for the 12 oz can is the quantity (size of can and quantity of cans shipped). This is recognized by the systems [either CBP's Automated Broker Interface/Automated Commercial Shipment (ABI/ACS) or FDA's Prior Notice System Interface (PNSI)] as separate prior notices but covered by a single shipment. This information has always been submitted via ABI/ACS as separate line items covered under a single shipment, and PNSI was designed to recognize the same situation. For purposes of prior notice, a line item is considered a single prior notice.

Different sizes of food products, especially low-acid canned foods such as canned tuna, are processed on different equipment lines and have different processing procedures and labeling. FDA enforcement efforts often focus on these specific issues, and it is important for us to know which specific foods are being offered for import. As stated in the preamble to the Prior Notice Interim Final Rule, "FDA believes that package size is necessary and part of product identity. The base unit of measure is a critical characteristic of product identity and is thus necessary for effective review of the prior notice information. Base unit is critical to processing safety requirements and is particularly important when evaluating the safety of low-acid canned foods. Both base unit and total quantity (which includes knowing the smallest 'package size') are necessary for response (examination) and communication with FDA and CBP staff at the border. As noted in FDA's 'Food Security Preventive Measures Guidance for Importers' (Ref. 17), they are also critical for food security examinations to determine if the amount ordered is the amount received. For example, if more was received than was ordered, the guidance recommends an investigation to determine the cause of the discrepancy as additional and unwanted articles may have been added to intentionally contaminate the shipment. If less product is received than ordered or than shipped, some of the product may have been intentionally diverted."

QUESTION:

7) FDA has determined that only half of the estimated 400,000 facilities that need to be registered with the Agency have in fact registered. Why are there so many facilities not yet in compliance? What is FDA doing to encourage regulated facilities to register?

RESPONSE:

In the registration interim final rule, FDA included its best estimate as to how many facilities would be required to register with FDA. It is possible that FDA's count of facilities covered under the registration requirement was an overestimation. However, because registration is a completely new requirement and covers so many food facilities, we also believe many facilities may still be unaware of the registration requirement, particularly small facilities. FDA continues to place a high emphasis on educating as many affected entities as possible of the requirements through outreach. On April 29, 2004, FDA completed domestic outreach meetings in nine cities as well as international outreach meetings in Mexico, Canada, the European Union, Japan, Korea, China, and Thailand for small businesses and other stakeholders on the registration and prior notice IFRs. FDA's international outreach has involved a foreign press conference in collaboration and cooperation with the Department of State, a Voice of America video teleconference, and efforts with USDA's Foreign Agricultural Service. Worldwide attachés disseminated the Registration and Prior Notice interim final rules, compliance policy guidance, and Questions and Answers. FDA will continue to conduct outreach in order to educate affected entities of the registration requirement.

QUESTION:

8) [There was no question 8 in the original document.]

QUESTION:

9) The final rule for identifying previous sources and subsequent recipients of food, which include food ingredients has not been issued yet. Given that, how does FDA envision responding to an incident that requires getting information from companies? What will the company be expected to do and what will FDA do? Does FDA expect to rely solely on the records provided by a company to investigate an incident?

RESPONSE:

You are correct that the final rule mandating establishment and maintenance of records to allow FDA to identify the immediate previous source and the immediate subsequent recipient has not yet been issued. However, section 306 of the Bioterrorism Act created a new section 414(a), "Records Inspection," in the FD&C Act, which became effective upon enactment and which authorizes FDA to access and copy records related to an article of food if: (1) the Secretary has a reasonable belief that the article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, and (2) the records are necessary to assist the Secretary in making such a determination. Under section 414(a), FDA may access records of any person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports food. In addition, section 306(b) of the Bioterrorism Act amends section 704(a) of the FD&C Act to give the Secretary authority to inspect "all records and other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. . . ." Under section 704(a), FDA may access records at an appropriate location of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports food. FDA is currently in the process of issuing guidance to its field staff on the appropriate procedures to follow in exercising this records access authority.

FDA does not expect to rely solely on a company's records to investigate an incident. FDA will use all available information, including intelligence data and inspectional data, to assist us in an investigation.

QUESTION:

10) We have heard from many within the food import community that FDA has not provided sufficient guidance on the practical applications of the Prior Notice provisions, and that even those importers contacting FDA with specific concerns or questions are not getting the assistance they need. Chief among these concerns is that without specific feedback from FDA as to why the Prior Notice filing is inadequate, it is difficult to make the changes necessary to assure that the importer is in compliance as of the proposed August 12, 2004 enforcement date. What is FDA doing to address this problem before the proposed August 12, 2004 enforcement date?

RESPONSE:

Beginning July 2004, FDA has been providing CBP with a list of specific shipments that have failed to correctly submit one or more prior notice data elements. The specific errors are identified as well as the names and contact information for the prior notice transmitter (usually the customs broker) and the prior notice submitter (usually the importer). CBP has then used this information to contact the transmitter (and through them, the submitter), describe the errors involved, and request that they recheck their records and correct the errors. If any questions arise about the correctness of the data in question, the transmitters are directed to contact FDA for further information. As a result of this feedback, many transmitters have identified and corrected systematic flaws in their software or data sources.

PNSI is an interactive system and will not accept incomplete prior notice information. Therefore, feedback is provided as the information is submitted.

FDA has published compliance summary guides that provide summary information about the level of compliance with the prior notice requirements, including data on the types of errors in submitted prior notices. The agencies are using the results of the compliance information to review some of the most problematic compliance areas to determine how to best improve compliance rates.

FDA and CBP have been working together to provide information on the requirements of this joint rulemaking. The two agencies have conducted numerous meetings with affected stakeholder groups. More information about our outreach efforts is provided in response to question 12 below.

QUESTION:

11) We understand that the current public comment period on Prior Notice has been extended to July 13 -- less than a month before proposed full enforcement begins. Is it possible that FDA can receive, review and implement changes suggested in these public comments before August 12?

Equally important, presuming FDA can make these changes by the proposed August 12, 2004 date; will the food import community have adequate time to make the changes needed on their end?

RESPONSE:

The Prior Notice IFR was published in the FR on October 10, 2003, (68 FR 58974). Comments on the IFR, which were accepted until July 13, 2004, for the second comment period, will be taken into consideration for the final rule we expect to publish in June 2005. Until the final rule is published, compliance with the requirements of the IFR is expected. Affected entities have had 10 months (from the October 10, 2003, publication date to August 12, 2004) to prepare for the requirements of the Prior Notice IFR.

FDA and CBP announced in December 2003 that the two agencies would provide a phase-in period until August 12, 2004. FDA recently published revisions to the Prior Notice CPG. Under the revised CPG, FDA and CBP are enforcing all provisions of the prior notice IFR , except for specified data elements (the registration number for the manufacturing facility or shipper; the Airway Bill number or Bill of Lading number; and the name and address of the ultimate consignee). For these violations, the two agencies should typically consider not taking any regulatory action until November 1, 2004. An electronic version of the revised CPG is available on the Internet at: *http://www.fda.gov/ora* under "Compliance References."

QUESTION:

12) a) As a key concern of the food importing public has been the need for additional education and outreach by FDA, we were very pleased to hear your affirmation during the hearing that such education and outreach was ongoing and would continue into the final phase of enforcement. The Committee would very much like to know more about FDA's outreach efforts, especially those conducted since the initial educational seminars held in December 2003. We specifically wish to hear how FDA is advising individual submitters of the problems they are having with their submissions and how these problems can be corrected prior to the proposed August 12, 2004 enforcement date.

RESPONSE:

FDA and CBP have conducted extensive domestic and foreign outreach to explain the rules to consumers and the food industry. As we mentioned in our reply to Question 7, on April 29, 2004, FDA completed domestic outreach meetings in nine cities as well as international outreach meetings in Mexico, Canada, the European Union, Japan, Korea, China, and Thailand for small businesses and other stakeholders on the registration and prior notice IFRs. FDA's international outreach has involved the collaboration and cooperation of the Department of State through a foreign press conference, Voice of America video teleconference, and USDA's Foreign Agricultural Service. Worldwide attachés disseminated the Registration and Prior Notice IFRs, compliance policy guidance, and Questions and Answers.

In addition to the many meetings we have conducted globally, FDA has developed and published a number of materials to explain the new requirements. We have posted these materials on our website and have announced their availability in FR notices and in e-mail messages to the thousands of persons who have signed up to be notified electronically of new items related to our implementation of the Bioterrorism Act. These materials include:

- Press releases, summary fact sheets, and slide presentations – each of which has been translated into eight languages (Spanish, French, Portuguese, Malay, Hindi, Arabic, German, Chinese, Japanese, and Polish);
- What You Need to Know Summary Booklets, a videostream of our October 28 satellite downlink meeting, and transcripts of the downlink – each of which has been posted on our website in the three official World Trade Organization languages (English, French and Spanish); and
- CPG Documents and Question and Answer Guidance Documents that answer questions we have received since publication that were not addressed in the preambles to the rules.
- Reports of U.S. regional and international meetings and educational materials focused on small entities and special situations such as international mail. This information can be found at: *http://www.cfsan.fda.gov/~pn/pnoview.html.* Information can also be found at the CBP website at: *http://www.customs.ustreas.gov/linkhandler/cgov/import/commercial_enforcement/bioterrorism/bta_fda_web.ctt/bta_fda_web.doc*

FDA has also made available step-by-step interactive tutorials and help menus that explain how to register electronically (a faster mode) or how to download or obtain by mail a hard (paper) copy of the registration form: *See http://www.fda.gov/oc/bioterrorism/bioact.html.*

The FDA Prior Notice Center has conducted over 11,000 educational outreach activities via phone and e-mail to a variety of sources seeking assistance with Prior Notice. For example, questions have been received from importers, brokers, filers, shippers, courier services, manufacturers, CBP Field Officers, U.S. and Foreign Embassies, and the general public. The Prior Notice Center staff have explained the Prior Notice requirements of the interim final rule and guided submitters through the electronic PNSI since Prior Notice started on December 12, 2003. Prior Notice Center staff are available 24 hours a day, seven days a week. They may be reached toll-free at 1-866-521-2297, internationally at 703-621-7728, or by e-mail at *Prior.Notice@ora.fda.gov.*

FDA has also established a Systems Help Desk that operates Monday through Friday, from 7:00 a.m. to 11:00 p.m. E.S.T. to provide assistance with inquiries related to the requirements of the interim final rules as well as computer-related technical

difficulties with either the prior notice or registration electronic systems. Individuals may contact the Help Desk by calling 1-800-216-7331, by sending a fax to 301-210-0247, or by sending an e-mail message to *furls@fda.gov*. To date, over 150,000 responses have been provided to inquiries received by telephone, fax, mail, e-mail and voice mail.

FDA and CBP also have worked with trade associations to include articles in their newsletters that inform affected parties of the duty to register and how to register. FDA has granted numerous press interviews with newspapers, magazines, and news stations around the world to explain the new requirements.

As part of its outreach activities, FDA has been reviewing the data in prior notice submissions and identifying those elements resulting in the most errors. In the first phase of informed compliance, food and animal feed products arriving without any prior notice were documented and the importers responsible for failure to provide prior notice were notified of this requirement. In this joint effort with CBP, FDA has been providing this information to CBP who in turn notifies the importer of inadequacies through an informed compliance letter. In the second phase of informed compliance, specific required elements with high rates of errors were evaluated. The transmitters receiving the most errors were identified and provided with a list of possible transmission errors. In each case, the importers or transmitters were able to submit questions regarding their errors or violations to FDA for review. If the importer or transmitter fails to correct their errors and continuously submits inadequate prior notice, CBP may refuse a shipment or invoke Civil Monetary Penalties for the violations. To date, FDA has received over 1025 responses to its outreach activities.

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Ranking Member
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

SEP 13 2004

Dear Mr. Dingell:

Thank you for your letter of July 12, 2004. With your letter, you submitted seven questions from Representative Charles A. Gonzalez following the June 25, 2004, hearing before the Subcommittee on Health on "Implementation of the Food Security Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act." Our responses to the questions are enclosed.

Thank you for your leadership in the enactment of this important legislation. We look forward to continuing to work with you and your staff on its implementation. If you have further questions, please let us know.

Sincerely,

Patrick Ronan

Patrick Ronan
Assistant Commissioner
for Legislation

Enclosure

cc: The Honorable Joe Barton
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-4306

The Honorable Michael Bilirakis
Chairman
Subcommittee on Health
House of Representatives
Washington, D.C. 20515-0909

The Honorable Sherrod Brown
Ranking Member
Subcommittee on Health
House of Representatives
Washington, D.C. 20515-3513

FDA Responses to Questions Submitted by Representative John D. Dingell on behalf of Representative Charles A. Gonzalez Following June 25, 2004, Hearing on Implementation of the Food Security Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act

1. Why are importers with no relationship to the food manufacturer being required to provide the FDA with a facility registration number on the Prior Notice?

FDA believed that requiring the manufacturer's registration number as part of prior notice reasonably achieved important goals for both the prior notice and the registration requirements in the Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act). The prior notice and registration requirements are intended to help FDA quickly identify and notify food facilities that may be affected by deliberate or accidental contamination of food and to help FDA more effectively target inspections to ensure the safety of imported foods.

Section 307, Prior Notice of Imported Food Shipments, of the Bioterrorism Act requires advance notice of imported food shipments and requires that the identity of the manufacturer be included in the prior notice submission. Requiring a facility's registration number, versus an alternative means of identification such as facility name or facility name and address, provides greater assurance that the facility identified in the prior notice is in fact the facility at which the article was produced. Without a registration number, it may be difficult to determine exactly which registered facility to associate with the article of food. Different firms may have the same or similar names and more than one firm may operate from the same location. Having the registration number in the prior notice submission will help FDA quickly identify the correct facility and thus will help us take appropriate action before the food enters the United States.

Section 305, Registration of Food Facilities, of the Bioterrorism Act requires that foreign facilities manufacturing food for consumption in the U.S. register. This section also requires that food be held at the port of entry if it is being imported from a foreign facility that is unregistered. To enforce these requirements in a way that would minimize the burden and not hold up the flow of commerce at the border, FDA required the manufacturer's registration number to be part of the prior notice submission.

FDA believes that implementing sections 305 and 307 in concert is reasonable. However, we are considering all comments on this approach to implementation that we receive. Before issuing the final rule, we will determine whether there are appropriate changes that should be made. In the meantime, FDA and Customs and Border Protection (CBP) recently issued a revised Compliance Policy Guide (CPG). This states that, except where the violation reflects a history of repeated conduct of a similar nature by a person who had been notified of such violations, FDA and CBP will typically not take any regulatory action through November 1, 2004, when the registration number of the manufacturing facility is inaccurate or invalid. The electronic prior notice system will continue to request a registration number in order to complete the submission process; however, the submitter may enter a "dummy" or default registration number during this period of enforcement discretion.

2. Concern has been expressed that importing competitors' samples for testing and analysis will be eliminated should the competing manufacturers' facility registration numbers be required in order to bring in the samples. Is it the FDA's intention to eliminate the critical business of importing competitors' samples for testing and analysis?

FDA concluded in the Prior Notice Interim Final Rule (IFR) that samples of food, including trade and market research samples, are subject to the Prior Notice IFR as they are "articles of food imported or offered for import" as stated in section 801(m) of the Federal Food, Drug, and Cosmetic Act (Volume 68, *Federal Register* (FR), page 58993). However, not all samples require a prior notice submission. If the samples are items that are in such early stages of research and development that they cannot yet be considered food under Title 21, *Code of Federal Regulations* (CFR) 1.276(b)(5), they would not be subject to prior notice requirements. An example of such an item is a substance being tested for possible preservative qualities before being tested in any food (68 FR 58993). Similarly, if the sample is in a form that is not an article of food, such as slurry of lettuce for pesticide analysis (as opposed to a head of lettuce) or a juice already packaged in a sterile sample container (as opposed to a can of juice) for heavy metal analysis, prior notice requirements would not apply.

It is not FDA's intention to eliminate the critical business of importing competitors' samples for testing and analysis. We received comments to the prior notice docket expressing similar concerns about the inability to acquire competitors' registration numbers when importing competitors' samples for testing. As we noted in our response to the first question, FDA and CBP recently issued a revised CPG that states that FDA and CBP will typically not take any regulatory action through November 1, 2004, when the registration number is inaccurate or invalid. Moreover, under the CPG, if food is imported for quality assurance, research or analysis purposes only (and not for human or animal consumption and not for resale), then FDA and CBP will typically not take any regulatory action when the registration number of the manufacturing facility is not provided. We will continue to consider these issues while we draft the final rule.

3. How does the FDA suggest U.S. distribution outlets handle perhaps damaged or outdated products returned for credit from foreign customers if the U.S. manufacturing facility is not required to register because the products were originally manufactured only for export?

The registration requirement in Section 305 of the Bioterrorism Act is facility-based and provides that a facility that manufactures/processes, packs, or holds any food (including animal feed) for consumption in the U.S. is required to be registered. Section 307 of the Bioterrorism Act requires advance notice of imported food shipments and requires that the identity of the manufacturer be included in the prior notice submission.

If the returned damaged or outdated foods are imported or offered for import and the manufacturing facility is not required to register, then the prior notice submission does not need to include the manufacturing facility's registration number. FDA plans to provide information and instructions to help submitters with this. Please note, however, that if food associated with the manufacturing facility is intended or reasonably expected to be consumed in the United States, then the facility would be required to be registered.

4. Why is it acceptable for personal imports of food articles not accompanying the recipient to merely list the manufacturer's name and address as shown on a product label on the Prior Notice but a commercial importer, perhaps of

the very same goods, must be required to have a direct relationship with the food manufacturer in order to bring the same product into the country?

The prior notice submission for an article of food sent by an individual as a personal gift (i.e., for non-business reasons) to an individual in the United States may include the name and address of the firm that appears on the product label instead of the name, address, and registration number of the manufacturer (21 CFR 1.281(a)(6) and (b)(5)). FDA explained in the preamble to the Prior Notice IFR that where the food shipment is of a personal versus commercial nature, the information readily available to the sender would be the information on the product label. Therefore, FDA allowed the name and address of the firm listed on the product label in lieu of the manufacturer's registration number (68 FR 58974-59006). FDA is aware that some commercial importers are facing problems getting the registration numbers of manufacturers. As discussed in our answers to questions 1, 2, and 7, we are considering all comments received during the public comment period on this issue and are working to determine whether there are appropriate changes that should be made.

5. Why does the FDA believe it is not capable of verifying facility registration without placing the burden on legitimate, third party importers? Can these reasons for shifting the burden of responsibility be cured through the Importation of Safe Food Act language?

FDA does not believe that burden-shifting accurately characterizes the requirement that a prior notice include the FDA registration number of the manufacturing facility of the article of food and that of the shipper associated with the article. As noted in response to question 1, this requirement implements Title 21, *United States Code* (U.S.C.), section 381(l) by ensuring that an article of food offered for import is from a duly registered facility. Congress mandated in 21 U.S.C. 350d(a)(3) that FDA assign a registration number to each facility. FDA has implemented this mandate through its food facility registration process, which assigns a unique registration number to each registered facility. The principal purpose of a registration number is to provide a unique and reliable way to identify a facility and to confirm its registration status. Were there to be an act of bioterrorism involving an article of food, accurate identification of the particular food manufacturing facility involved would in most circumstances be critical to the appropriate investigation and resolution of the incident. Given the volume of registered facilities (which currently exceed 200,000), using an alternative means of identification, such as facility name or facility name and address simply cannot provide the same level of assurance that the proper facility has been identified. In addition, a facility's registration number is not as readily available as a manufacturer's name and address, which generally may be easily obtained from sources such as a telephone book. Thus, requiring an exporter to provide in the prior notice the registration number of the manufacturing facility for the article provides greater assurance that the facility identified in the prior notice is in fact the facility at which the article was produced.

Whether the Importation of Safe Food Act further clarifies this issue depends upon the meaning of "verify" in the proposed revision of 21 U.S.C. 381(l)(1). For the reasons articulated above, accurate, reliable, and efficient identification of a food facility, which is a prerequisite of verifying the facility's registration status, arguably requires the use of a unique identifier, such as use of the facility's registration number.

6. By what means can an importer verify whether a food product being considered for import and distribution in the U.S. is manufactured in a registered facility prior to import in order to avoid refusal of entry?

The registration status of a food facility is information that can be obtained directly from the management of the manufacturing facility. Congress stipulated in section 305 of the Bioterrorism Act that FDA's list of registered facilities and registration documents that

FDA receives, as well as any information derived from these documents that would disclose the identity or location of a specific registered person, are not subject to disclosure by FDA under the Freedom of Information Act. However, disclosure of such information by the facility itself is not prohibited. FDA expects that, generally, foreign suppliers and their customers will resolve this question as part of their business relationship.

7. What is the risk of postponing full implementation of the existing FDA rules while the Congress more fully hears testimony on the Importation of Safe Food Act and participates in some additional outreach to the trade in order to make sure that in the guise of security legislation we haven't sacrificed critical domestic businesses and global trade industries?

Since the prior notice interim final rule became effective in December 2003, FDA and CBP have been reviewing the data quality of prior notice submissions. This review has revealed that failure to provide the registration number is still a relatively common deficiency. In addition, FDA has received comments that some importers are facing problems getting the registration numbers of manufacturers, as some manufacturers are unwilling to release that information. As we noted in our responses to questions 1 and 2 above, FDA and CBP have recently issued a revised CPG that states that FDA and CBP will typically not take any regulatory action through November 1, 2004, when the registration number of the manufacturing facility is inaccurate or invalid. We will likewise determine whether there are appropriate changes that should be made to the interim final rule that both satisfy the language and intent of the Bioterrorism Act and do not compromise the security of the food supply.